IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS, INC., ROCHESTER DRUG CO-OPERATIVE, INC., MEIJER, INC., MEIJER DISTRIBUTION, INC., AMERICAN SALES COMPANY, LLC, WALGREEN CO., SAFEWAY INC., SUPERVALU INC., and HEB GROCERY CO. LP, et al.,	:	
Plaintiffs,	:	**Civ. No. 12-3824 CONSOLIDATED**
v.	:	**INDIRECT PURCHASER ACTION**
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,	:	
Defendants.	:	

DEFENDANT WARNER CHILCOTT'S OPPOSITION TO INDIRECT PURCHASER PLAINTIFFS' AMENDED MOTION FOR CLASS CERTIFICATION

PUBLIC REDACTED VERSION

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I. INTRODUCTION

The Indirect Purchaser Plaintiffs fail to satisfy Rule 23 in many ways, and this Court should deny their renewed motion for class certification. Plaintiffs have now had two chances to justify certifying their amorphous and unwieldy classes of "end-payers" of Doryx, but this latest attempt is no better than the first—and only adds complexity and individual issues.

Indirect Purchaser Plaintiffs IBEW[1] (**Florida** and **Nevada** indirect purchasers) and IUOE[2] (**West Virginia** indirect purchasers) ask this Court to certify three state law damages classes and one injunctive relief class.[3] Particularly under the demanding requirements of recent Supreme Court and Third Circuit authority, this Court should reject Plaintiffs' motion. *See Comcast v. Behrend*, 133 S. Ct. 1426 (2013); *Carrera v. Bayer Corp.*, 727 F.2d 300 (3d Cir. 2013); *In re Hydrogen Peroxide*, 552 F.3d 305 (3d Cir. 2008). Indeed, just yesterday another federal court presiding over a pharmaceutical antitrust class action rejected the indirect purchasers' class certification motion—and Dr. Rausser's conclusions supporting class certification—for reasons fully applicable here, as discussed further below. *See In re Skelaxin (Metaxalone) Antitrust Litigation*, 1:12-md-02343, Dkt. No. 508, at 26–27 (E.D. Ten. Jan. 30, 2014).

In this Court's Order of November 20, 2013 (Dkt. No. 434), the Court ruled that Plaintiffs had failed to meet the requirement of numerosity. Order at 1. In response, Plaintiffs have obtained another declaration from Dr. Rausser on class certification and modified their

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[1] International Brotherhood of Electrical Workers Local 38, Health and Welfare Fund.

[2] International Union of Operating Engineers Local 132 Health and Welfare Fund.

[3] Mem. of Law in Support of Indirect Purchaser Plaintiff's Amended Mot. for Class Cert., Dkt. No. 449 (Jan. 7, 2014) ("Plaintiffs' Amended Brief"), at 2–4. Despite the pendency of Defendants' motion to dismiss IOUE's late-filed complaint, IOUE joins the amended motion for class certification, adding a proposed West Virginia class to the mix. Defendants oppose certification of the West Virginia class, even though no discovery has been received from IOUE, and reserve the right to raise arguments based on that discovery (or any related, necessary discovery) once it has been obtained. IOUE informed Defendants that it joins with all the prior expert reports previously submitted on behalf of IBEW and the proposed classes of indirect purchasers.

proposed class definitions. This additional declaration and briefing by Plaintiffs reveals that the proposed classes fail to meet not only the numerosity requirement but also several other requirements of Rule 23:

First, Plaintiffs cannot demonstrate with classwide proof that each member of the proposed classes suffered impact (*i.e.*, antitrust injury) from the allegedly unlawful conduct. Among other things:

- Plaintiffs' impact analysis ***does not match*** their theory of liability—directly violating *Comcast*. Discovery forced Plaintiffs to concede that the launch of new Doryx products, standing alone, was not unlawful. But for class certification Plaintiffs rely solely on an impact analysis by Dr. Rausser[4] that ***assumes away all Doryx product improvements***, directly contradicting Plaintiffs' liability theory.

- Plaintiffs modified their class definition to correct problems identified by Defendants in the first round of briefing on class certification, but the new class definitions still include scores of class members who have suffered no impact. For example, Plaintiffs now seek to exclude from their class definitions consumers who used only ***coupons***, and the consumer portion of all "coupon transactions," but doing so only requires greater individualized inquiry and leads to an overstatement of both class membership and damages, as Defendants' expert, Dr. Pierre Yves-Cremieux, explains in his expert report accompanying this brief.

- Plaintiffs' theory of impact is based on ***misleading "averages"*** that hide significant variations in price, generic penetration rates, co-pays and other cost-sharing levels, and other critical inputs. As Dr. Cremieux explains, analyzing the variation hidden by these averages reveals that at least two of the three subgroups within the proposed classes—uninsured consumers and insured consumers—include substantial numbers of members ***who would not have been harmed*** by a delay in generic Doryx capsules. Despite efforts to gerrymander the classes by "redefining" them, Plaintiffs offer no way, short of individual inquiry, to identify such uninjured members of the proposed classes.

- Plaintiffs' impact analysis ***ignores key factors*** that affect the actual and but-for world prices paid by putative class members—both key elements of Plaintiffs' impact analysis. These factors (such as use of coupons, samples, insurance deductibles, risk-sharing agreements, pass-on through premium increases) show that ***many putative class members were not impacted*** and that Plaintiffs have offered no formulaic way to ascertain the members of the proposed classes. Instead, individualized inquiry would be required.

[4] Dr. Rausser's opinions fail to meet minimum standards of relevance and reliability for a host of reasons. Defendants' will file a separate motion to exclude Dr. Rausser's declarations, reports and testimony pursuant to Rule 702 and *Daubert*.

- Plaintiffs offer no evidence that, if generic Doryx capsules were launched in 2006 (as Plaintiffs assume), Warner Chilcott would have abandoned its Doryx franchise, folded up the tents, and not pursued any product improvements. Plaintiffs' assumptions fly in the face of the evidence, which shows that (1) each product change was a material improvement, (2) Warner Chilcott pursued product changes to meet competition from other branded anti-acne products, and (3) Warner Chilcott in fact pursued a new branded Doryx product (its 200 mg tablet) ***after*** Mylan entered with generic forms of Doryx in 2011. If, as the evidence shows, Warner Chilcott likely would have offered competing Doryx tablet products in the "but-for" world, then Plaintiffs cannot credibly assume that all class members would have purchased a generic capsule in the but-for world. This failure eviscerates Plaintiffs' impact and damages models.

Second, Plaintiffs' damages model fails under Rule 23(b) for the reasons listed as well as the following:

- Plaintiffs rely on unsupported assumptions, do not account for consumers and/or third-party payers ("TPPs") ***who actually would benefit*** from a delay in generic entry and fail to account for the degree to which insurer class members ***passed on*** any claimed overpayment to premium payers and others.

- Plaintiffs offer no methodology for taking the ***lump-sum damages pool*** calculated by their proposed expert and assigning damages to individual class members. Plaintiffs' economist claims that all uncertainties in assignment/allocating damages would be addressed in some undefined "claims administration" process at the end of the case. But ***mere promises*** to develop an adequate damages methodology in the future do not satisfy Rule 23, particularly in light of *Comcast*.

Third, the proposed classes fail to satisfy several elements of Rule 23(a)—numerosity, ascertainability, and adequate class representation—for essentially the same reasons that lead Judge Collier yesterday to reject Dr. Rausser's opinions and deny an end-payers class certification in *In re Skelaxin*, another so-called "delayed generic entry" case. In addition to the *Skelaxin* decision, a recent trilogy of Third Circuit cases, *Marcus*, *Carrera*, and *Hayes*, similarly have put ascertainability under a microscope.

- ***Speculation about Numerosity and Ascertainability***. Plaintiffs' numerosity proof is little more than speculation because their proposed experts, among other things, used inapposite data and failed to account for key variables that would remove substantial numbers of potential members from the class. Moreover, Plaintiffs nowhere explain how they plan to ascertain class membership without complicated, individualized inquiry. For example, the complex web of risk-sharing arrangements among insurers, employers,

pharmacy benefit managers, and other intermediaries, as well as the role of the federal and state governments in funding even "private" insurance (through, for example, Medicare Part D plans), would require individualized inquiry to identify which entity in fact was responsible (*i.e.*, "on the risk") for reimbursing Doryx prescriptions and thus a potential class member. Plaintiffs have offered no methodology for doing so.

- ***Inadequate class representatives***. Plaintiffs cannot even show that they themselves are members of the three proposed Rule 23(b)(3) classes, [redacted] Nor have Plaintiffs, union health plans, offered any explanation as to how they would be capable of zealously protecting the interests of insured and uninsured consumers. At a bare minimum, there is an ***inherent conflict*** between benefit plans, such as Plaintiffs, and their insureds, since any claimed overpayment must be divided between insurer and insured—each side having an incentive to maximize its recovery at the expense of the other. Nor can Plaintiffs' claims be viewed as "typical" of those of cash paying consumers, on the one hand, or of nationwide insurance giants and self-funded employer groups, on the other.

Fourth, Plaintiffs' proposed nationwide Rule 23(b)(2) class for ***injunctive relief*** must be rejected as an inferior mechanism for pursuing such relief. Plaintiffs themselves, together with multiple other plaintiffs, already are pursuing injunctive relief against Defendants, and the relief they seek is speculative and undefined. There is no need for a costly and time-consuming class action mechanism to seek duplicative injunctive relief, and in any event Plaintiffs' injunctive relief claims are too ill-defined to support standing.

Accordingly, this Court should deny Plaintiffs' motion for class certification.

II. FACTUAL BACKGROUND

This Court is well aware of the factual background of this novel antitrust litigation, including from the earlier briefing of the Indirect Purchaser Plaintiffs' Motion for Class Certification.[5] For the Court's convenience, Defendants are simultaneously submitting a Factual Background Appendix In Support of Defendants' Opposition, which provides an updated summary of the background facts.

[5] *See, e.g.*, Defendant Warner Chilcott's Opposition to Indirect Purchasers Plaintiff's Motion for Class Certification, May 16, 2013, ECF No. 234.

A. Plaintiffs' Revised Claim: New Drug Introductions Are Lawful, But If Coupled with Withdrawal of Old Products Can Be Unlawful if the *Sole* Purpose Is to Thwart Generic Entry

Plaintiffs have made a number of concessions that narrow the unspecified "product hopping" allegations from the complaint. In light of the overwhelming evidence undermining the foundation of their claims that "product hopping" is anticompetitive under the Sherman Act, Plaintiffs now concede that the launch of new products alone, even ones that do not offer new medical benefits to patients, could not cause antitrust injury or otherwise violate the antitrust laws. Plaintiffs now argue that it is not Warner Chilcott's new product launches (or its shift in marketing support), but rather the combination of the launch of new products and the alleged withdrawal from the market of the older versions that Plaintiffs challenge as unlawful.

Plaintiffs' proffered expert, Dr. Kesselheim summarized Plaintiffs' position as follows:

> ***I do not contend, nor do I understand the Plaintiffs to be arguing, that Warner-Chilcott/Mayne cannot introduce and lawfully promote new versions of Doryx, such as a tablet—despite the fact that it offered no medical benefit to patients over the capsule version—or that Warner-Chilcott/Mayne must continue to promote the capsule after launching the tablet.*** Rather, it was Warner-Chilcott/Mayne's admitted 'anti-generic' strategy that accompanied its introduction of the tablet version that harmed purchasers and consumers. That strategy included taking affirmative steps to eliminate the capsule market by, for example, stopping production of Doryx capsules and buying up much of the remaining inventory in anticipation of the approval of a capsule version from a generic competitor, so that patients with prescriptions for Doryx capsules could not receive them and would need to have their physicians write new prescriptions for the tablet version.[6]

Dr. Rausser, Plaintiffs' economist for class certification, specifically agreed with this concession by Dr. Kesselheim [redacted]

[6] Report of Aaron Kesselheim in Response to Expert Report of E.M. (Mick) Kolassa, dated Oct. 18, 2013, ¶ 2 (emphasis added) ("Kesselheim Response Rep."); s*ee also* Plaintiffs Amended Br. at 1 (Warner Chilcott "intentionally produced new formulations of Doryx with either no benefits – or at worst an inferior product – *and* withdrew prior formulations of Doryx.") (emphasis added).

[redacted]

These concessions of course, while they still fall short of bringing Plaintiffs' case into line with the Sherman Act, should not come as a great surprise because the introduction of new products, supported by marketing efforts, is procompetitive. As the Court knows, Warner Chilcott vigorously denies, however, that such pro-competitive conduct can be viewed as anticompetitive even if combined with the discontinuation of the old product. Warner Chilcott Mot. to Dismiss IBEW Compl., ECF No. 101, dated Oct. 31, 2012, at 15–16; Warner Chilcott Mot. to Dismiss Mylan Compl., ECF No. 84, dated Oct. 1, 2012, at 12–15. Indeed, the discontinuance of older versions of products when newer ones are introduced is commonplace—for example, Toyota stops selling and promoting 2012 Camrys when the new 2013 models arrive (even if the 2013 model is similar to the 2012).

[7] Rausser Merits Dep. Tr. (Ex. 109) at 200:10–16.

[8] *Id.* 198:20–199:11.

[9] *Id.* at 199:19–200:3

[10] *Id.* at 199:18–200:3.

[11] *Id.* at 209:2–210:8; *see* Rebuttal Report of Gordon Rausser, Dec. 23, 2013, ¶ 58 (Ex. 1) ("[T]he standard implied by my report is that manufacturers should refrain from a pattern of product modifications and related activities whose sole purpose and effect is thwarting generic entry.") ("Rausser Rebuttal Rep."). [redacted]

Given these concessions, Plaintiffs explain that their alleged "***damages all flow from Defendants' initial switch or product hop from capsules to tablets***" in 2005, the only alleged "product switch" even allegedly involving both a new product launch and immediate discontinuation of an older product.[12] However, as explained below, Dr. Rausser followed a different set of assumptions in evaluating impact and calculating damages.

B. Plaintiff's Three Proposed End-Payer Classes—Each Is Diverse and Includes Differently-Situated Members

The two named plaintiffs propose to serve separately as the sole class representative for their separate classes. IBEW proposes to serve as the representative for two state law classes (Florida and Nevada) under Rule 23(b)(3). IUOE proposes to serve as the representative for an additional state law class (West Virginia) under Rule 23(b)(3). Both IBEW and IUOE propose to serve as representatives for a federal, injunction-only, class under Rule 23(b)(2).

The proposed Florida indirect purchaser class is defined to include persons or entities "who reimbursed for, or indirectly purchased, other than for resale, branded Doryx in the state of Florida, from any of the Defendants, other than for resale," from 2008 forward, and excludes Defendants and related entities and individuals, as well as "fully-insured health plans, i.e. plans that purchased insurance from another third party payer covering 100% of the Plan's reimbursement obligations to its members; all governmental entities; insured individuals covered by plans imposing a flat dollar co-pay that was the same dollar amount for generic as for brand drug purchases; and insured or uninsured individuals who purchased branded Doryx with a coupon and never purchased branded Doryx without a coupon."[13] The proposed Nevada and West Virginia indirect purchaser classes use the same definition, substituting "Nevada" and

[12] Plaintiffs Amended Brief at 12 (emphasis added).

[13] *Id.* at 2–3.

"West Virginia," respectively, for "Florida" as the relevant state at issue.[14] Plaintiffs' amended Rule 23(b)(3) class definitions also include the following condition: "For the purpose of computing damages and allocating or distributing any damages awarded in this case, no individual consumer class member shall be entitled to receive damages for any Doryx purchase made using a Warner Chilcott consumer coupon.[15] The proposed federal injunction class seeks to encompass "[a]ll persons or entities in the United States and its territories who reimbursed for, or indirectly purchased, other than for resale, branded Doryx from any of the Defendants," during the same time period and subject to the same exclusions as the two state law classes. *Id.*

IBEW is a union health and welfare trust fund that provides a pharmacy benefit to approximately 6,000 members. IBEW is based in Ohio and has few members residing in Florida or Nevada. [redacted]

[14] *Id.* at 3–4.

[15] *Id.* [redacted]

[redacted]

IUOE is a union health and welfare trust fund similar to IBEW that is located in West Virginia and provides pharmacy benefits to approximately 3,000. [redacted]

Each of the proposed classes is widely diverse, consisting of at least three categories of members:

1. Uninsured Consumers

Uninsured consumers are those who lack pharmacy benefits and therefore pay cash for their pharmaceuticals. The pricing of both brand and generic drugs to such cash payers depends on the prices set by the respective manufacturers, as well as the markups imposed by middlemen in the pharmacy distribution chain. In the case of branded drugs, the manufacturer ships to wholesalers, who in turn ship to retail pharmacies (as well as clinics, hospitals and other healthcare facilities).[21] In the case of generic drugs, manufacturers also ship to wholesalers, but

[redacted] Defendants have not yet taken discovery from IUOE and thus reserve the right to file a supplemented submission (if necessary). [redacted]

[21] Kaiser Report, Follow the Pill: Understanding U.S. Commercial Pharmaceutical Supply Chain, at 8 (Ex. 144).

often bypass the wholesaler and sell directly to various large retail pharmacy chains, mass merchandisers and supermarket chains. *See, e.g.*, *Valley Drug Co. v. Geneva Pharms., Inc.*, 350 F.3d 1181 (11th Cir. 2003) (noting by-pass phenomenon) [redacted]

As Plaintiffs' own economist, Dr. Gordon Rausser, has conceded (in opposing certification in a recent case involving the same kind of end-payer class action at issue here), pricing and markups at each level of those distribution chains varies considerably, which allows average prices to mask individual price differences. To take just the markups by retail pharmacists, Dr. Rausser explained: "Pharmacies' markups to cash-paying customers . . . *vary considerably*, depending, for example, on the pharmacy's location and business strategy. Some pharmacies are located in mass merchandising stores, which use low drug prices to increase the foot traffic in their stores as a way to sell other products. . . . [O]ther pharmacies, such as those in rural areas, have little competition and can mark up their drug prices considerably."[22] Retail pharmacists are also known to take more substantial markups on generic drugs than they do for branded ones. According to Dr. Rausser, "Because the cash register price paid by uninsured consumers varies significantly from pharmacy to pharmacy, the use of an 'average' retail price obscures important differences among class members' purchases."[23] As discussed below, in this case Dr. Rausser relies upon just such averages.

[22] Redacted Declaration of Gordon Rausser, Ph.D., in support of Defs. Opp. to Pls.' Mot. for Class Cert., *Weiss v. AstraZeneca*, Dkt. No. BC323107 (Cal. Sup. 2008), ¶ 113 (emphasis added) ("Rausser Nexium Decl.") (Ex. 103).

[23] *Id.* ¶ 55. A 2004 study by the New York City Council found vast differences in the prices charged at retail within a single neighborhood. *See* "Prescription Drug Prices: All Over the Map" Staff Report to the Committee on Oversight and Investigations, February 2004, at 2 (Ex. 104). In just the borough of Manhattan, the study found cash prices for Prevacid varied by as much as $78.05 per prescription. *Id.* at 17. Prices for the allergy medication Allegra varied from a low of $61.95 to a high of $106, a difference of over 70%. *Id.* For the arthritis drug Celebrex,

Adding to the diversity in pricing are discounts, coupons and free samples that were offered by Warner Chilcott on branded Doryx, but which would not have been offered by a generic. [redacted] Again, in the words of Plaintiffs' economist: "Because generic drug manufacturers seldom offer incentives of this type, any analysis that fails to factor in the effect of consumer coupons and rebates will provide a deceptive picture of the relative costs of the [brand] and [generic]."[26]

As noted, the proposed definition of each Rule 23(b)(3) damage class seeks to exclude ***transactions*** involving coupons, supposedly in response to Defendants' evidence that "coupon payments create a situation where certain consumer Class members do not experience an adverse impact."[27] Plaintiffs' "coupon transaction" carve out, however, does not address the individual inquiry required by the diversity in prices paid by uninsured consumers to determine whether uninsured consumers were impacted and is flawed as a matter of basis economics.[28]

For example, assume the retail price for one month's supply of a branded pharmaceutical was $100 and a particular uninsured consumer needed a three month supply. If the patient received free samples covering the first month and then used a coupon worth, $40 for the next month, but no coupon for the third month, the patient's effective cost for the three month supply

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the study found that pharmacy prices in New York City varied from $60.16 to $128.00 for the same quantity and strength – a difference of over 100%. *Id.*

[redacted]

[26] Rausser Nexium Decl. (Ex. 103) ¶ 39.

[27] Rausser Rebuttal Decl. ¶ 20.

[28] *See infra* Part III.D.1.b.

would be $160 ($0 plus $60 plus $100). If the generic price was $60 per month, that patient's effective cost for the three months would be $180 ($60 times 3), which would be $20 more than for the brand when coupons and samples were factored in. Such a consumer would not be harmed by a delay in the availability of the generic. But, Plaintiffs' limited coupon transaction carve out would award that consumer $40 ($100 cost of brand in month three less $60 cost of generic in month three) in damages because only the third transaction would be considered part of the class. The $60 benefit from the first two months is improperly ignored.

As explained below, instead of evaluating which uninsured consumers, if any, would have been impacted, Plaintiffs arbitrarily exclude all uninsured consumer transactions involving a coupon, which has the effect of overstating both consumer impact and damages.[29]

2. Consumers with Insurance

Consumers with prescription drug insurance coverage often pay the pharmacy only a co-payment or deductible for covered prescriptions. Their insurance provider pays the rest under an agreement between the insurance provider (or its pharmacy benefits manager) and the pharmacy.[30] The types of cost-sharing mechanisms vary not only between and within insurance providers, but also over time.[31]

While Plaintiffs have excluded patients with flat co-pays, Plaintiffs fail to account for other variations that would lead to insured consumers not being impacted. Some plans have deductibles, in which the patient is responsible for all pharmacy expenditures up to a dollar limit,

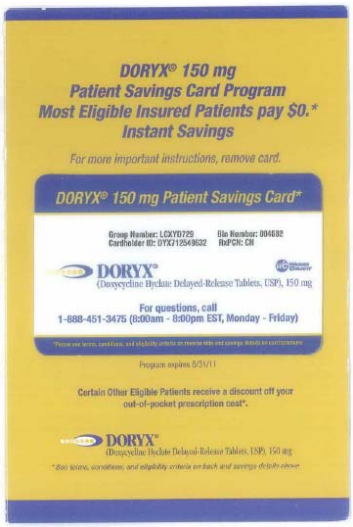
[29] Plaintiffs' Amended Mot. for Class Cert. at 2–3; Rausser Merits Dep. Tr. (Ex. 109) at 347:21–348:24 [redacted]

[30] Expert Decl. of Gordon Rausser ¶ 100.

[31] Kaiser Family Foundation Annual Survey 2012 ("Kaiser 2012") (Ex. 147) at 149–50, 153.

and thereafter the insurance plan covers all prescription expenditures, whether brand or generic.[32] If a patient needs Doryx for the first time after she has exceeded the deductible, and there is no cost sharing after the deductible has been met, then she would not be impacted by a delay in generic availability. Here, the question of impact will depend on the timing of the prescription in relation to other health care expenditures, as well as the deductible limit of the particular plan, a highly individualized inquiry.

Other plans have differential co-pays, in which the co-pay for a generic drug is lower than that for a branded pharmaceutical. The number of co-pay tiers and the spreads between tiers vary widely plan to plan.[33] And even where a differential co-pay is in place, the question whether an individual consumer is impacted by a delay in generic entry will depend on the sampling and coupon issues discussed above (in the context of uninsured consumers). For example, Warner Chilcott offered a coupon (pictured below) that reduced consumers' co-pay to $0.



[32] *See* Kaiser 2012 (Ex. 147) at 148 (19% of covered patients nationally enrolled in high deductible plans have 100% of prescription costs once plan deductible is met), at 150 (5% covered by plans in which there is no cost sharing after deductible is met).

[33] Kaiser 2012 (Ex. 247) at 148–49; [redacted].

The types of plans offered run the gamut of terms. Indeed, major insurers such as United Health Care or Blue Cross/Blue Shield themselves offer myriad different plans to their millions of insured patients.[34]

Dr. Rausser has conceded that assessing any individual patient's experience is an individualized undertaking. For example, "a covered consumer's co-pay is not predictable. One must have specific information about the consumer's particular prescription drug plan and the date when the purchase was made in order to know the co-pay applicable to the target drug purchase and/or to the purchase of a hypothesized alternative therapy on that same day."[35] Dr. Rausser also acknowledged that changing coverage status is important and is difficult to track in any formulaic manner: "[E]ven fundamental characteristics (such as whether an individual is insured or uninsured) will change over time (as he or she is employed or unemployed) in ways which cannot be tracked."[36] As discussed below, no such individualized consideration is found in Dr. Rausser's analysis in this case, and his efforts to minimize this failure are easily rejected.

3. Third Party Payers (TPPs)

A TPP (*e.g.*, an insurance company, self-funded employer health plan) pays what remains of the amount owed to the pharmacy after deducting the co-pay provided by the consumer. A TPP may pay the full amount where, for example, the plan's deductible has been exceeded. The amount a TPP will pay for branded and generic prescriptions is negotiated between the TPP (or its pharmacy benefit manager) and the pharmacy. As Dr. Rausser admitted, such negotiated reimbursement rates "*vary considerably* according to pharmacy and [TPP]" and depend on such

[34] *See, e.g.*, United Health Group 2013 Form 10-K, at 2 (Ex. 149).
[35] Rausser Nexium Decl. (Ex. 103) ¶ 42.
[36] *Id.* ¶ 160.

things as the number of covered patients the TPP controls, the number of pharmacies competing in the geographic area, and other factors.[37]

In order to assess a TPP's net cost to reimburse for a particular drug, one must also consider rebates that the TPP may receive, directly or indirectly, from the drug's manufacturer so the drug will be eligible under the plan for coverage, often referred to as being "on formulary."[38] Dr. Rausser explained: "[M]anufacturers of branded pharmaceuticals often enter into agreements with [TPPs] under which the manufacturer agrees to pay them a rebate if the drug is placed on their formulary, given a favorable formulary position, and/or reaches certain sales levels."[39] Dr. Rausser also agreed that manufacturer rebates are "*highly variable* . . . [O]ne would expect significant variability in the rebates a single manufacturer pays to different third party payers."[40]

In commenting on the complexities across all the types of members of an end-payer class such as this one, Dr. Rausser stated as follows:

> The cost of a particular [drug] therapy depends upon a host of factors specific to the individual consumer or third party payer members of the proposed class. Among these factors are the pharmacy where the drug was purchased; the prescription drug plan providing insurance coverage and its specific benefit design; the daily dose taken; the duration of use; the number and amount(s) of coupons redeemed by the consumer; the number of free samples received by the consumer; the number and amount(s) of manufacturer rebates received by the third party payer or its PBM; . . . the contractual relationship between the third party payer and its PBM; and the time period over which the drug was purchased. Each of these individual factors is highly variable across proposed class members.

[37] *Id.* ¶ 123.

[38] *See Id.* at ¶ 44 ("To calculate the *actual* cost to the third party payer, the third party payment [to the pharmacy] must be adjusted for manufacturer's rebates.").

[39] *Id.* ¶ 44.

[40] *Id.* ¶ 129.

Id. ¶ 98. [redacted] Dr. Rausser reached his class certification opinions without evaluating these complexities.[42]

C. Dr. Rausser's Proposed Methodology to Assess Impact and Damages Contradicts Plaintiffs' Liability Theory and Impermissibly Relies on Averages and Generalizations That Mask Individual Issues

Plaintiffs depend entirely on Dr. Rausser to carry their burden of showing that classwide impact and damages can be proven using common evidence. To conclude that all members of the proposed classes would have been impacted by delayed generic entry, Dr. Rausser follows assumptions that contradict the facts and Plaintiffs' position in the case. Dr. Rausser also relies on top-line averages and generalizations; he does not discuss the complexities and individual issues that he took great pains to enumerate in his analysis discussed above.

Instead, Dr. Rausser uses the following "logic" to arrive at his conclusion:

- While quickly dismissing any medical or other benefits of Warner Chilcott's follow-on Doryx product set forth by Defendants' experts,[43] Dr. Rausser asserts that they represented "immaterial" improvements; then assumes that, in the but-for world in which generic capsules would have entered in 2006, Warner Chilcott would have abandoned not only the launch of its Doryx 75 and 100 mg tablet products, which occurred in 2005, 8 months ***before*** a generic Doryx capsule product was approved, but also any further improvements – leaving the world limited to Doryx 75 and 100 mg capsules and generic equivalents.[44]

[41] Rausser Merits Dep. Tr. (Ex. 109) at 100:20–101:5.

[42] Plaintiffs cannot claim that Dr. Rausser's opinions in *Nexium* are inapplicable here because (i) his Nexium opinions addressed marketplace facts, such as the pricing and risk-sharing complexities associated with pharmaceutical distribution, that do not vary depending on the product, and (ii) the Nexium litigation concerned analogous allegations—claims that end payers purchased a product that was supposed to be an improvement but supposedly was not and that in the but-for world end payers would have purchased a different, cheaper product than the one actually purchased. Dr. Rausser's efforts to evade his *Nexium* opinions miss the mark. He cannot contest that the Plaintiffs' amended class definition, which excludes consumer coupon transactions and consumers with flat co-pays alleviates any potential conflict. As explained in Section III.D.1, Dr. Rausser still does not take into account brand loyalists, samples provided to consumers, and consumers who were uninjured because of couponing.

[43] Rausser Rebuttal Rep. ¶¶ 35–38.

[44] Rausser Decl. ¶¶ 17, 37, 121; *see also* Rausser Merits Rep. ¶¶ 86, 88.

- Without analyzing the wherewithal or interest of any generic firm to do so, Dr. Rausser assumed in his Class Certification Declaration that in the but-for world "at least half a dozen" generic firms would introduce generic forms of Doryx capsules in July 2006.[45] In his Merits Report, [redacted]

- Having assumed away any Doryx improvements that might have competed against his assumed generic capsule entrants, Dr. Rausser then purports to develop a classwide average "overcharge" by comparing the average actual prices for branded Doryx tablets with but-for prices of hypothetical generic capsules, ignoring that these products are not equivalent (*i.e.*, they are not AB-rated).[47]

- In his Class Certification Declaration, Dr. Rausser then adopts an average generic penetration rate which he bases on academic literature addressing products having nothing to do with Doryx or acne medications.[48] He later amends this approach and applies a generic conversion rate [redacted], and pricing [redacted], again failing to consider the actual Doryx conversion rates and pricing that occurred when generic versions of Doryx entered the market.[49]

- He applies this penetration rate to the total sales of Doryx during the class period—providing, in his view, a universe of affected sales, *i.e.*, sales that he claims would have been generic in the but-for world.[50]

- He then applies his average "overcharge" to his affected sales total to arrive at a total pot of "overcharge" damages.[51]

Among other things, Dr. Rausser made no effort in his original Class Certification Declaration to assess the kinds of individualized "no-impact" scenarios discussed above for both insured and uninsured consumers, the degree to which the combination of manufacturer rebates, co-pays and sampling would impact the net prices paid by individual TPPs,[52] the degree to which

[45] Rausser Decl ¶¶ 21, 122.

[46] Rausser Merits Rep. ¶¶ 88, 90, 95.

[47] Rausser Decl. ¶¶ 118, 122; *see also* Rausser Merits Rep. ¶¶ 133, 148

[48] Rausser Decl. ¶ 124.

[49] Rausser Merits Rep. ¶ 145.

[50] Rausser Decl. ¶ 123; *see also* Rausser Merits Rep. ¶ 153.

[51] Rausser Decl. ¶ 128; *see also* Rausser Merits Rep. ¶ 156.

[52] Dr. Rausser does purport to perform a "sensitivity analysis" to gauge whether the combination of manufacturer rebates and co-pays leads the average TPP to be indifferent to generic entry. Rausser Decl. ¶¶ 110–14. As

the TPPs passed on any assumed cost increases in the premiums they charge, the impact of risk sharing agreement, or the impact of deductibles and benefit maximums. His superficial attempts to analyze and quickly dismiss these issues after the fact in later reports cannot hide the individualized "no-impact" situations shown by the evidence.[53]

Moreover, Dr. Rausser offers no methodology, formulaic or otherwise, for assessing how to divide the aggregate damages figure he calculates among the members of the putative classes.[54] And his recent submission on numerosity fails to remove numerous, unimpacted putative class members and thus measures nothing relevant.

III. ARGUMENT

A. The Standard for Certifying Classes Has Become More Exacting, Particularly in Light of the Supreme Court's Recent Decision in *Comcast v. Behrend*, which Reinforced the Demanding Requirements of Rule 23, Including Consideration of Certain Merits Issues

1. Plaintiffs Have the Burden of Showing that the Proposed Classes Satisfy Each of the Requirements of Rule 23

Class actions are "an exception to the usual rule that litigation [be] conducted by and on behalf of the individual named parties only." *Comcast*, 133 S. Ct. at 1432 (quoting *Califano v. Yamasaki*, 442 U.S. 682, 700–701 (1979)). Rule 23 sets forth Plaintiffs' burden when seeking to

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discussed below, *see infra* Part III.C.1.c.ii, that analysis examines some but not all relevant variables, and only underscores the need for individualized inquiries. Cremieux Decl. ¶¶ 66–70.

[53] *See, e.g.*, Cremieux Decl. ¶ 17–20; Cremieux Merits Rep. ¶ 102, 105.

[54] IPP Mot. at 32–33; Rausser Decl. ¶¶ 119–20, 123–24, 126–27; Cremieux Decl. ¶ 21, 103–14. Dr. Rausser also references the filing of citizen petitions, Rausser Decl. ¶ 37, but [redacted] Nor does IBEW argue that any Warner Chilcott citizen petition was a sham. *See, e.g.*, IBEW Opp. to Motion to Dismiss, at 27 ("Plaintiff does not challenge Defendants' September 2011 Citizen Petition, nor its NDAs, as 'sham petitions.'").

Dr. Rausser also offers opinions on such merits issues as whether Warner Chilcott possesses monopoly power or can be viewed to have anticompetitive intent. Rausser Decl. ¶¶ 34–36. While we disagree with his conclusions, we do not address them at this class certification stage. They will be refuted at the appropriate time.

certify a class action.[55] For each of the four proposed classes, Plaintiff must satisfy the adequacy, typicality, numerosity, and commonality criteria of Rule 23(a). In addition, IBEW and IUOE must satisfy the predominance and superiority requirements under Rule 23(b)(3) for the Nevada, Florida, and West Virginia classes, which requires that "the court find[] that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). "If proof of the essential elements of the cause of action requires individual treatment, then class certification is unsuitable." *In re Hydrogen Peroxide*, 552 F.3d 305, 311 (3d Cir. 2008) (quoting *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 172 (3d Cir. 2001)). For the injunction class, IBEW must satisfy Rule 23(b)(2), which requires proof that Defendants have "acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole." *McNair v. Synapse Group, Inc.*, 2010 WL 4777483, at *3 (D.N.J. Nov. 15, 2010).

2. This Court Must Resolve Merits Disputes if Needed to Assess Rule 23 Requirements

Trial courts are now required to rigorously evaluate whether plaintiffs have satisfied each and every requirement of Rule 23, through evidentiary proof, even if that means reaching "merits" issues. *See Hydrogen Peroxide*, 552 F.3d at 317 ("Because the decision whether to certify a class requires a thorough examination of the factual and legal allegations, the court's rigorous analysis may include a preliminary inquiry on the merits.") (internal citations omitted); *In re New Motor Vehicles Can. Exp. Antitrust Litig.*, 522 F.3d 6, 24 (1st Cir. 2008) ("[I]nquiry

[55] *See, e.g.*, *Shady Grove Orthopedic Assoc. v. Allstate Ins.*, 130 S. Ct. 1431, 1447–48 (2010) (holding that all claims in putative class action in federal court are subject to Rule 23 as "a Federal Rule governing procedure is valid whether or not it alters the outcome of the case in a way that induces forum shopping").

into the merits at the class certification stage is not only permissible but appropriate to the extent that the merits overlap the Rule 23 criteria.").[56] This "rigorous analysis" is important because an overly permissive certification of classes can violate the Rules Enabling Act, which bars procedural rules from abridging, enlarging, or modifying any substantive rights. 28 U.S.C. § 2072(b); *Wal-mart Stores Inc. v. Dukes*, 131 S. Ct. 2541, 2561 (2011); *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 613 (1997); *Hohider v. United Parcel Serv., Inc.*, 574 F.3d 169, 185 (3d Cir. 2009). For example, in an antitrust case, the Third Circuit has held, "individual injury (also known as antitrust impact) is an element of the cause of action; to prevail on the merits, every class member must prove at least some antitrust impact resulting from the alleged violation." *Hydrogen Peroxide*, 552 F.3d at 311. If a court certified a class and then proceeded to trial with a class methodology that assumes, but cannot actually establish, that all class members were impacted by the challenged conduct, the defendant's substantive rights would have been abridged in violation of the Rules Enabling Act. Likewise, such analysis minimizes the unfairness concerns inherent in permitting class actions, whereby the mere certification of a nationwide class can place "'insurmountable pressure' on a defendant to settle, even where the defendant has a good chance of succeeding on the merits." *Regents of U. of Cal. v. Credit Suisse First Bos., Inc.*, 482 F.3d 372, 379 (5th Cir. 2007) (citation omitted); *see Hydrogen Peroxide*, 552 F.3d at 310 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007)) ("Certain antitrust class actions may present prime opportunities for plaintiffs to exert pressure upon defendants to settle weak claims.").

The *Comcast* Court reiterated the district courts' obligation to carefully scrutinize class certification motions. In *Comcast*, the Supreme Court reversed a decision of the Third Circuit,

[56] Sister courts of appeals are all in agreement that a merits inquiry is only precluded if it is not necessary to determine a Rule 23 requirement. *See Hydrogen Peroxide*, 552 F.3d at 317.

and made clear that district courts can no longer wait until the "merits" stage to address issues that bear on the requirements of Rule 23—including the requirement of Rule 23(b)(3) that common issues predominate in terms of both antitrust injury and damages. As the Court made clear, "[i]f anything, Rule [23](b)(3)'s predominance criterion is even more demanding than Rule 23(a). . . . Rule 23(b)(3), as an 'adventuresome innovation,' is designed for situations 'in which class-action treatment is not as clearly called for' . . . . That explains Congress's addition of procedural safeguards for (b)(3) class members beyond those provided for (b)(1) or (b)(2) class members (*e.g.*, an opportunity to opt out and receive notice), and the court's duty to take a 'close look' at whether common questions predominate over individual ones." 133 S. Ct. at 1432.[57]

The "close look" mandated by *Comcast* will "frequently entail 'overlap with the merits of the plaintiff's underlying claim.'" *Id.* Reaching the merits includes resolving disputes among conflicting expert testimony and/or resolving the admissibility of proffered expert testimony. *See, e.g., West v. Prudential Sec., Inc*., 282 F.3d 935, 938 (7th Cir. 2002) (observing that a "district judge may not duck hard questions by observing that each side has some support, or that considerations relevant to class certification may also affect the decision on the merits," and finding that where "the judge . . . thought the clash [of experts] enough by itself to support class certification and a trial on the merits," that "amounts to a delegation of judicial power to the

[57] Since *Comcast*, courts and commentators have noted that the Supreme Court's decision has made the requirements for class certification more exacting. *See, e.g., Phillips v. Asset Acceptance, LLC*, 2013 WL 1568092, at *3 (N.D. Ill. Apr. 12, 2013) (acknowledging that certain prior class certifications may not survive recent decisions, such as Comcast, which "may portend a tightening of class certification standards"); *Roach v. T.L. Cannon Corp*., 2013 WL 1316452, at *3 (N.D.N.Y. Mar. 29, 2013) (denying class certification in light of *Comcast*); *Martins v. 3PD, Inc*., 2013 WL 1320454, at *8, n. 3 (D. Mass. Mar. 28, 2013) (noting that in *Comcast*, the Supreme Court "has called . . . into question" the proposition that "courts generally find the predominance requirement satisfied even if individual damages issues remain"); Class Certification Vacated on Ascertainability, Numerosity Grounds, 17 No. 8 Consumer Fin. Serv. L. Rpt. 1 , 2 (2013) ("In *Marcus*, the 3d Circuit confirmed the equal importance of all elements of Rule 23, including ascertainability and numerosity. Citing recent U.S. Supreme Court precedent, including *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541 (2011) and *Comcast Corp. v. Behrend*, 133 S. Ct. 1426 (2013), as well as its own opinion in *Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305 (3d Cir. 2008), the 3d Circuit confirmed that even deep and significant inquiries into a claim's merits are required if necessary to address the class certification requirements.").

plaintiffs, who can obtain class certification just by hiring a competent expert"); *In re Methionine Antitrust Litig.*, 204 F.R.D. 161, 165 (N.D. Cal. 2001) (evaluating expert's opinion and concluding that "[the expert's] method will not determine whether an individual class member has in fact been injured by the price-fixing conspiracy); *In re Agric. Chems. Antitrust Litig.*, 1995 WL 787538, at *5–7 (N.D. Fla. Oct. 23, 1995) (finding that impact could not be shown on classwide basis because, inter alia, Plaintiffs' expert essentially assumed classwide impact and data contradicted his conclusions); *Dry Cleaning & Laundry Inst. of Detroit, Inc. v. Flom's Corp.*, 1993 WL 527928, at *5–6 (E.D. Mich. Oct. 19, 1993) (finding that plaintiff's expert had "not conducted a thorough empirical analysis of the market and fare structures involved . . . .").

Evaluation of an expert's conclusions plainly is part of the "rigorous analysis" that Rule 23 requires. District courts are not obligated to accept as true any assertion that a testifying expert is willing to make without regard to the facts.

B. Plaintiffs Cannot Satisfy Rule 23(b)(2)'s Predominance Requirement by Relying on an Expert Whose Impact Analysis and Damages Calculations Do Not Match Plaintiffs' Liability Theory

Plaintiffs rely entirely on Dr. Rausser's opinion to try and meet their burden of showing that common issues predominate on both antitrust injury and damages. A basic requirement for class certification, however, is that the expert's methodology for assessing impact and damages match the plaintiff's claims. Without that fit, a plaintiff could obtain certification by hiring an expert to speak only to the Rule 23 requirements without regard for whether the case itself was appropriate for class treatment.

In *Comcast*, the Supreme Court reinforced the requirement that, "at the class certification stage (as at trial), any model supporting a plaintiffs' damages case must be consistent with its liability case, particularly with respect to the alleged anticompetitive effect of the violation." 133

S. Ct. at 1433 (citations omitted). Where an economic expert makes no effort to connect his economic analysis to the facts of the case, his testimony is completely irrelevant. *See id.*; *see also Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *Tyger Const. Co. v. Pensacola Const. Co.*, 29 F.3d 137, 144 (4th Cir. 1994) (trial court erred in allowing expert testimony "based on assumptions which find no support in the record"); *Three Crown Ltd. P'ship v. Salomon Bros., Inc.*, 906 F. Supp. 876, 894 (S.D.N.Y. 1995) (excluding expert opinion where opinion was based on a series of assumptions about how plaintiffs would have acted but for the defendants' alleged manipulation, and noting the opinion "would rest upon numerous assumptions without the type of support required under the case law"); *Baker v. Urban Outfitters*, 254 F. Supp. 2d 346, 354 (S.D.N.Y. 2003) (granting motion to exclude proffered expert report and testimony, finding expert's opinion to be irrelevant where expert calculated damages based on benchmark not at issue in the case); *Johnson Elec. N. Am. Inc. v. Mabuchi Motor Am. Corp.*, 103 F. Supp. 2d 268, 286 (S.D.N.Y. 2000) (excluding expert analysis where the expert failed to point to any specific transactions that supported the expert's analysis or conclusions). Plaintiffs fail this basic requirement here.

1. Dr. Rausser's Approach Fails Because He Does Not Follow Plaintiffs' Liability Case

Plaintiffs' liability case now focuses on the withdrawal of older versions of products as a necessary element of what made Defendants' conduct unlawful. As Plaintiffs' experts (Dr. Kesselheim and Dr. Rausser) explained, launching new versions of Doryx was not, standing alone, anticompetitive, even assuming (contrary to fact) that those new versions did not represent improvements over the prior versions. Instead, Plaintiffs' theory is that Defendants caused harm through the "combination" of launching a new product and taking the older product off the

market.[58] It was these allegedly "affirmative steps" to "eliminate" the market for the prior product by, for example, "stopping production" and "buying up inventory" that Plaintiffs claim caused harm.[59]

However, Dr. Rausser bases his impact and damages models on an assumption that the but-for world would be one in which Warner Chilcott introduced *no tablet products or any later versions of Doryx at all*. This approach conflicts with Plaintiffs' liability theory and undisputed facts. It is undisputed that in the actual world Warner Chilcott launched a series of tablet products that each achieved substantial sales in the marketplace. And Plaintiffs' own liability theory would allow the launch of new Doryx tablets, as long as the older versions were kept on the market for some period of time. Accordingly, Dr. Rausser's simplistic approach (no new Doryx products; competition frozen at capsules in 2005) is in tension with and ignores the but-for world specifically authorized by Plaintiffs' liability theory.

This point is critical and dooms Plaintiffs' motion. Antitrust plaintiffs are entitled to recover only for *competition-reducing* aspects of the claimed antitrust wrongdoing. *See City of Pittsburgh v. W. Penn. Power Co.*, 147 F.3d 256, 266 (3d Cir. 1998) (affirming dismissal of complaint where "'utilities' purported antitrust violation can only be said to have been competition-neutral and as such, is not actionable") (citing *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990) ("The antitrust injury requirement ensures that a plaintiff can recover only if the loss stems from a competition-reducing aspect or effect of the defendant's behavior.")) *Pool Water Prods. v. Olin Corp.*, 258 F.3d 1024, 1034 (9th Cir. 2001) ("If the injury

[58] Kesselheim Response Rep. ¶ 2; Rausser Merits Rep. ¶ 30 ("The strategy adopted by defendants had four key parts: 1) implementation of immaterial changes to Doryx that would delay pending ANDA approvals; 2) aggressive conversion of all patients and doctors to each "new" formulation, regardless of cost, and 3) complete discontinuation and withdrawal of the prior formulation so as to make generic entry unprofitable.").

[59] *See, e.g.*, Kesselheim Response Rep. ¶ 2.

flows from aspects of the defendant's conduct that are beneficial or neutral to competition, there is no antitrust injury, even if the defendant's conduct is illegal *per se*.") (citations omitted); *Alpern v. Cavarocchi*, No. Civ. A. 98-3105, 1999 WL 257695, at *5 (E.D. Pa. Apr. 28, 1999) (same).

This means that any damages model or assessment of antitrust impact must properly distinguish between competition-reducing and competition-enhancing (or at least competition-neutral) conduct. *See Comcast*, 133 S. Ct. at 1434 (rejecting damages model as "a methodology that identifies damages that are not the result of the wrong"); *Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 152 F.3d 588, 593 (7th Cir. 1998) ("Any nonconspiratorial factors likely to have made the prices charged by the [defendant] higher than the prices charged by other health-care providers had to be taken into account in order to make a responsible estimate of the prices that [plaintiff] would have paid had it not been for the conspiracy."). Moreover, expert testimony must be tethered to the "real economic world" and cannot avoid inconvenient marketplace facts. *OSB Antitrust Litig.*, 2007 WL 2253425, at *29.

There can be no doubt that Dr. Rausser's model fails this basic test. Specifically, Dr. Rausser assumes away lawful conduct—the launch of the Doryx tablet products—and constructs a model that is incapable of assessing impact and damages on a classwide basis assuming the existence of even one, let alone more than one, of the Doryx tablet product introductions. For example, taking just the introduction of the 75 and 100 mg Doryx tablets in 2005, one cannot assume, as Dr. Rausser does, substantial generic erosion and price declines in a market where branded Doryx tablets, branded Doryx capsules, and generic capsules are being sold—as

Plaintiffs' liability theory would allow.[60] Each physician and consumer would have to decide whether to select branded Doryx tablets, generic or branded Doryx capsules, or a different therapy altogether. Dr. Rausser's approach accounts for none of this, and this failure is fatal.

Indeed, as Dr. Cremieux discussed in his Merits Responsive Report and Rebuttal Report, this scenario most likely would lead to essentially zero damages recoverable by Plaintiffs, which is probably why Dr. Rausser chose to ignore it. As Dr. Cremieux explains, if it were deemed anticompetitive for Warner Chilcott to withdraw capsules, that does not exclude or prevent Warner Chilcott from launching, marketing, and promoting new products.[61] The but-for world in which that occurs would be "essentially the same as the actual world, resulting in no damages to [P]laintiffs."[62] [redacted][63] Dr. Rausser's attempt to assume such competition away in his analysis violates what the Supreme Court warned is the "first step in a damages study": translation of the allegedly "harmful event into an analysis of the economic impact of that event." *Comcast*, 133 S. Ct. at 1435.

2. Plaintiffs Cannot Avoid the Required Impact and Damages Analysis by Claiming Warner Chilcott Had No Incentive to Launch Doryx Tablets

Dr. Rausser cannot save his analysis by claiming that Warner Chilcott had no reason to launch its tablet products, that is to say, that Warner Chilcott had no reason to compete lawfully. Instead of efforts to meet competition or innovate, according to Dr. Rausser, each product improvement was part of a "pattern" of conduct undertaken solely to "thwart" generic

[60] Cremieux Merits Rep. ¶ 36; Rebuttal Expert Report of Pierre-Yves Cremieux, Dec. 23, 2013 ("Cremieux Rebuttal Rep."), ¶ 12.

[61] Cremieux Merits Rep. at ¶ 14.

[62] *Id.* at ¶¶ 35–36.

[63] Rausser Merits Dep. Tr. (Ex. 109) at 199:18–200:3.

competition.[64] Thus, the argument apparently goes, when de-coupled from the unlawful "withdrawal" activity, the lawful product launch activity would not have been undertaken by Warner Chilcott. Dr. Rausser offers no basis to support his assertions, which are belied by his own analysis and testimony, and which ignore the fundamental dynamics of a competitive marketplace.

a. No Support for Dr. Rausser's Conclusions

Instead of addressing the marketplace facts that drove Warner Chilcott's decisions, [redacted] But, there is nothing improper about having a strategy "anti" to your competitors. In fact, the very purpose of the antitrust laws is to foster tough, aggressive competition. *See, e.g.*, *RJ Reynolds Tobacco Co. v. Cigarettes Cheaper!*, 462 F.3d 690, 696 (7th Cir. 2006) ("[A]s we remark frequently in antitrust litigation, 'cutthroat competition' is a term of praise rather than condemnation. . . . Businesses need not love their rivals (or firms that compete with their customers . . . .") (internal citations omitted); *Answerphone, Inc. v. Bell Atl. Corp.*, 955 F. Supp. 418, 432 (W.D. Pa. 1996). Ford has an "anti-Chevy" strategy, and McDonalds has an "anti-Burger King" strategy—and the antitrust laws encourage those strategies. [redacted] Thus, the fact that Warner Chilcott had a desire to stay ahead of its generic competitors actually undercuts Plaintiffs' position because it shows that Warner Chilcott could not stand still. Its legitimate economic incentive would be to

[64] Rausser Rebuttal Rep. at ¶ 58.

[65] Rausser Merits Dep. Tr. (Ex. 109) at 291:4-16.

launch new Doryx products before a generic came to market (and even in some instances after that occurred).[66]

[redacted]

Tellingly, Dr. Rausser could not identify when Defendants' conduct crossed the anticompetitive line he purports to draw. [redacted]

[66] Cremieux Merits Rep. ¶¶ 37–38.

[67] Rausser Merits Dep. Tr. (Ex. 109) at 239:5–19.

[68] *See Id.* at 229:17–25 (changing the formulation to meet competition); 305:11–306:2 (believing that the new formulation would reduce the risk of esophageal ulceration); *see* Fact App. at C (fact section discussing evidence regarding product improvements).

[69] Rausser Merits Dep. Tr. (Ex. 109) 219:19–223:7; *id.* at 45:10–12 [redacted]; *see also Id.* (Ex. 109) (at 223:2-7 [redacted]

[70] Rausser Merits Dep. Tr. (Ex. 109) at 238:713.

[71] *Id.* 238:7–13 (indicating that he "offered no opinion about what point in time [Defendants] crossed the line aside from the fact that beginning with the latter part of 2008, the line had been crossed").

[redacted]

Dr. Rausser's other contentions regarding Warner Chilcott's innovation lack merit.[73] He contends that because there was no increase in price from the capsule to the tablet, there was consequently no improvement in the latter over the former.[74] As Dr. Cremieux explained, this contention [redacted][75] [redacted][76] Dr. Rausser's claim that Warner Chilcott would have had no incentive to launch tablet products *after* generic entry likewise misses the mark.[77] This contention cannot explain away the initial Doryx tablet launch, undertaken 10 months before generic entry, and ignores the fact that Warner Chilcott launched its 200 mg tablet product well after generic competition for Doryx had been established.[78]

As *Comcast* teaches, Plaintiffs bear the burden of proving with *evidence* that the assumptions underlying their certification conclusions are justified. They have utterly failed to do so here. Indeed, as explained in the next section, overwhelming evidence shows that Warner

[72] *Id.* at 243:15–23 (admitting that he "ha[s] not made any assessment of attribution among each of the alleged wrongful actions").

[73] Rausser Class Cert. Dep. Tr. (Ex. 117) at 88:18–20; Rausser Merits Dep. Tr. (Ex. 109) at 45:10–12. [redacted]

[74] Rausser Merits Rep. ¶¶ 43–44.

[75] Cremieux Decl. ¶ 80.

[76] *Id.*

[77] Rausser Rebuttal Rep. ¶¶ 70–74 (relying on an analysis of FDA data to support his conclusion that "it is very rare for brand companies to develop any new formulations of a brand drug after it has experienced generic entry.").

[78] Cremieux Merits Rep. ¶ 32.

Chilcott had every financial incentive to innovate and launch new products, even if it were not permissible to withdraw the replaced products.

b. Warner Chilcott's Incentives to Launch Improved Products

The evidence establishes strong and clear economic incentives for Warner Chilcott's product innovations. As explained in detail in Part C of the Factual Appendix, the pressures of competition forced Warner Chilcott to explore innovation and adapt to a changing marketplace or risk being left behind.[79]

For example, Defendants developed a tablet formulation in response to esophageal issues (risk of ulceration) presented by Doryx capsules.[80] Esophageal ulceration issues, although rare, were sufficiently serious to lead to concerns from international regulatory agencies and revocation of approval.[81] Moreover, Doryx competitors specifically referenced esophageal "sticking" issues when marketing their products against Doryx. [redacted] Fougera also promoted Adoxa in advertisements as a "[s]mall easy-to-swallow tablet" as compared to doxycycline hyclate capsules and also claimed that "78% of patients surveyed prefer tablets vs. capsules."[83] Other competitors marketed both tablet and capsule products. Medicis launched its Dynacin tablet product in 2003, despite the fact that

[79] Having failed to offer evidence in its opening submission that the Doryx products were not improvements, Plaintiffs cannot be permitted to surface with medical or other evidence on reply. Such sandbagging tactics are not tolerated by the courts. *See Laborers' Int'l Union v. Foster Wheeler Energy Corp.*, 26 F.3d 375, 398 (3d Cir. 1994) ("[a]n issue is waived unless a party raises it in its opening brief, and for those purposes 'a passing reference to an issue . . . will not suffice to bring that issue before this court.'") (citations omitted).

[80] [redacted]

[81] *See* Fact App. at C.2.

[redacted]

[83] Adoxa Advertisement, WC3364650 (Ex. 23).

generic capsule versions had been on the market for several years, and experienced success in converting patients to tablets.[84] This landscape made a tablet version of Doryx a virtual necessity.

[redacted] Because major U.S. wholesalers "prefer as long an expiration date as possible to be assured that the product can move through the supply chains and reach the patient for administration prior to product expiry,"[87] and many products can be returned if the expiration date is within six-months' time,[88] Warner Chilcott preferred a product with a longer shelf-life [redacted] to prevent unnecessary wholesaler returns and a better product for its consumers. The '161 patent itself also provided the likelihood of a period of freedom from competition from a generic version of a Doryx tablet, an important, lawful motivation Dr. Rausser ignores.[89]

[84] [redacted]

[85] *See* Fact App. at C.2.

[86] *See* Fact App. at C.2.

[87] Robbins Rep. ¶ 154.

[88] *Id.*

[89] Cremieux Merits Rep. ¶¶ 38–39.

The tablet product also provided more options for future development. Unlike capsules, tablets could be scored to allow greater flexibility in creating and altering treatment regimens (with the flexibility to split tablets and to crush and sprinkle over applesauce), increased ease in complying with treatment regimens, assistance to patients who find it difficult to swallow larger pills, and a reduction in co-payments and reimbursements by third party payers.[90] Competitors started to focus on dosing flexibility, such as weight-based dosing and a broad array of dosing options for Doryx allowed it to meet this competition. [redacted] At that time, Warner Chilcott only marketed 75 mg and 100 mg capsules. As Defendants' expert dermatologist explained, the benefits from the improved Doryx products provided sales representatives with marketing messages that would have been well-received by physicians.[92]

Against the entirety of this backdrop—stability issues, risk of esophageal ulceration, revocation of doxycycline capsule approval in various jurisdictions, attacks from competitors on "sticky" capsules, other brand and generic competition, and protection of a valuable commercial investment—Mayne and Warner Chilcott developed and marketed the Doryx tablets.[93] It is specious to suggest that Defendants would have undertaken *none* of these competitive actions if they were required to continue to market older products upon launching newer versions.

[90] Webster Rep. ¶¶ 17–19; *see also* Leyden Rep. ¶¶ 83–86 (describing the importance of dosing flexibility for the treatment of patients with acne). [redacted]

[92] Webster Rep. ¶¶ 16, 18–20.

[93] *See* Fact App. at C.2.

In fact, even if Warner Chilcott did not launch a tablet product, given Warner Chilcott's commitment to dermatological products, it had strong incentives to (and likely would have) launched a 150 mg capsule product, which would have allowed Warner Chilcott to mirror Adoxa's successful launch of that strength, and to satisfy physician demand for a higher strength doxycycline product.[94] Dr. Rausser's analysis does not (and cannot) consider the impact of this valid scenario.[95]

Further, perhaps the strongest indication that Warner Chilcott would not have abandoned its Doryx franchise in the face of generic competition is found in its real-world conduct with respect to its 200 mg Doryx tablet product. [redacted] Although Mylan entered with generic tablet versions of the 150 mg tablet beginning in January 2011, Warner Chilcott, after facing generic competition already on the market for the first time, did *not* abandon the 200 mg tablet as Dr. Rausser's hypothesis would suggest. Instead, it continued to pursue the application, which FDA approved on April 12, 2013. Warner Chilcott launched the 200 mg product in July 2013 and, in just a few months, has achieved a high rate of sales and has taken away some sales from manufacturers selling the 150 mg Doryx tablet.[96] (The 200 mg product also has the benefit of a newly approved dosing regimen for the treatment of chlamydia.)[97]

In short, Plaintiffs' (and Dr. Rausser's) assumptions aside, there can be no doubt that the Warner Chilcott had many incentives for launching Doryx tablets products as they, in fact,

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[94] *See* Fact App. at C.4; Cremieux Merits Rep. ¶¶ 42–45.

[95] Cremieux Merits Rep. ¶¶ 47–49.

[96] *See, e.g.*, Frederick Flyer Dep. Tr. at 216:2–6 (Ex. 154) [redacted].

[97] Q1 2013 Warner Chilcott Earnings Call Transcripts at 7 (Ex. 59); Prescribing Information: Doryx® (doxycycline hyclate delayed-release tablets), 80 mg, 100 mg, 150 mg, and 200 mg for Oral use § 2.1, *available at* http://www.wcrx.com/pdfs/pi/pi_doryx_200.pdf.

offered clear medical, economic, and competitive benefits over prior formulations. Dr. Rausser's hypothetical but-for world assumes away, without justification, these innovations and thus must be rejected.

* * *

The above fit issues doom Plaintiffs' certification claims. However, even if the Court disagrees, there are still a litany of reasons why Plaintiffs' proposed classes cannot be certified.

C. Courts Refuse to Certify Proposed Indirect Purchaser Classes in the Pharmaceutical Industry due to Complexities that make Certification Improper

Plaintiffs' motion also fails because there are a host of individualized issues that preclude certification. Indeed, even prior to *Comcast*, courts have been suspect of indirect purchaser class actions like this one in the pharmaceutical industry because the distribution and reimbursement complexities in the industry create a host of individualized issues regarding impact and damages. For example, in *K-Dur*, where a proposed class of end-payer plaintiffs alleged that a patent settlement agreement unlawfully delayed entry of a generic product, the district rejected the class, finding that plaintiffs did not satisfy the predominance requirement. Special Master's Report and Recommendation on the Indirect Purchaser Plaintiffs' Amended Motion for Class Certification, at 26, *In re K-Dur Antitrust Litig.*, No. 01-1652 (JAG) (Consolidated Cases), MDL Docket No. 1419 2008 WL 2660723(D.N.J. Mar. 27, 2008). The court explained that (1) some TPPs paid more for the generic than the brand because the reduction in price of the generic did not offset the lower co-pay received by the TPP for the generic, and (2) consumers with "no co-pay or a flat co-pay" paid the same amount out-of-pocket regardless of whether they purchased the brand or the generic. These "variable co-pays structures" meant that significant numbers of

TPPs and consumers "presumably" suffered no injury. *Id.* at 22. As shown below, all these issues are present here.

Similarly, in *Sheet Metal Workers*, a proposed class of end payer plaintiffs alleged that defendants filed sham patent infringement litigation aiming to prevent generic manufacturers from entering the market for generic Wellbutrin SR. *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 2010 WL 3855552, at *2 (E.D. Pa. Sept. 30, 2010). The court rejected the proposed class. *Id.* at *31. Based on the complex web of co-pay structures and variations among these structures, the court found that several categories of consumers—consumers who first purchased Wellbutrin in a generic form and did not pay co-insurance; consumers who paid the same co-payment for both generic and branded drugs; and brand loyalists—suffered no impact and could not be identified and excluded from the class in a formulaic manner. *Id.* at *26, 30 (citing *Reed v. Advocate Health Care*, 268 F.R.D. 573 (N.D. Ill. 2009)).[98] Likewise, in *In re Skelaxin*, the court very recently refused to grant class certification to an end payer class in a pharmaceutical antitrust context because the complicated set of contracts and risk sharing agreements between third-party payers made individual inquiry necessary to determine which consumers and entities were part of the class. 1:12-md-02343, Dkt. No. 508, at 26–27 (E.D. Ten. Jan. 30, 2014).

A few courts, applying pre-*Comcast* standards for assessing common impact, partially certified classes where, unlike here, it was possible to identify clearly non-impacted class members—usually because the generic in question had already entered and real-world impact

[98] *See also, e.g.*, *A&M Supply Co. v. Microsoft Corp.*, 654 N.W.2d 572 (Mich. 2002) (denying certification of indirect purchasers of Microsoft products under Michigan law); *Ludke v. Philip Morris Cos.*, 2001 WL 1673791 (D. Minn. Nov. 21, 2001) (denying certification of indirect purchasers under Minnesota law); *Kerr v. Abbott Labs*, 1997 WL 314419 (D. Minn. Feb. 19, 1997) (same); *In re Brand Name Prescription Drugs Antitrust Litig.*, 1994 WL 663590 (N.D. Ill. Nov 18, 1994) (denying certification of indirect purchaser class under Alabama law).

assessments were possible. Such class members could then be excluded. *See In re Wellbutrin XL*, 282 F.R.D. 126, 131, 145 (E.D. Pa. 2011) (excluding consumers with flat co-pays and brand-loyal patients where generic entry had actually occurred and data was available); *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 216 (E.D. Pa. 2012) (excluding flat co-pay patients where real-world entry data available); *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326 (E.D. Mich. 2001) (excluding persons who did not purchase the generic form and flat co-payers where real-world entry data was available); *In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672 (S.D. Fla. 2004) (excluding brand loyalists where real-world entry data available); *In re Relafen Antitrust Litig.*, 221 F.R.D. 260 (D. Mass. 2004) (excluding those who paid the same for brand and generic, based on real-world data). Here, since Plaintiffs focus on a generic that was only briefly on the market (generic Doryx capsules), no real-world data is available.

The only post-*Comcast* case to partially certify an indirect purchaser class, is not to the contrary and actually supports Defendants. *In re Nexium*, No. 12-md-02409-WGY, 2013 WL 6486917 (D. Mass. Dec. 11, 2013). There the court recognized that insurmountable individualized issues may arise in indirect purchaser cases. While the defendants in *Nexium* did not have the appropriate proof which reached the level of preventing certification of damages classes, here, Defendants have provided a plethora of evidence demonstrating individualized issues predominate the proposed classes Plaintiffs seek to certify.

Thus, there is no easy "fix" to the no-impact issue here and the proposed classes must be rejected in their entirety. Similar to *K-Dur* and *Sheet Metal Workers*, Plaintiffs have not sufficiently overcome the fact that there is no common impact among class members here.

D. Individual Issues Predominate on the Question of Impact

The Third Circuit has warned that, at the class certification stage, "impact often is critically important for purposes of evaluating Rule 23(b)(3)'s predominance requirement because it is an element of the claim that may call for individual, as opposed to common, proof." *Hydrogen Peroxide*, 552 F.3d at 311; *see also, e.g., Ala. v. Blue Bird Body Co.*, 573 F.2d 309, 327 (5th Cir. 1978) ("'[I]mpact is a question unique to each particular plaintiff and one that must be proved with certainty;" common evidence must allow "each plaintiff [in the proposed class] . . . [to] prove that this conspiracy . . . did in fact cause him injury."); *In re Indus. Diamonds Antitrust Litig.*, 167 F.R.D. 374, 382 (S.D.N.Y. 1996) ("On a motion for class certification, the issue confronting [a district] court is whether the proof necessary to demonstrate impact as to each class member is particular to that class member, in which case individual questions concerning impact would overwhelm the common questions concerning the existence and scope of the alleged conspiracy."). Antitrust impact "requires each individual class member to show that they were adversely impacted." *In re Chocolate Confectionary Antitrust Litig.*, 289 F.R.D. 200, 220 (M.D. Pa. 2012). Thus, even if antitrust wrongdoing can be shown with common proof, *every* class member, representative and absent, must prove impact. *OSB*, 2007 WL 2253425, at *7 (Diamond, J.) ("Plaintiff must establish that each class member has, in fact, been injured by the alleged conduct.").[99]

Courts reject class certification where impact is not capable of proof at trial through evidence that is common to the class rather than individual to its members. *See New Motor Vehicles*, 522 F.3d at 20 (1st Cir. 2008) ("In antitrust class actions, common issues do not

[99] Plaintiffs cannot avoid *OSB* by focusing on the class members who had purchased OSB themselves (class certified) and ignoring putative class members who purchased houses containing OSB (certification denied). The price complexities here, driven by insurance coverage, brand loyalty, cost sharing coupons, samples, etc., are similary to the latter, not the former, and likewise raise individualized issues.

predominate if the fact of antitrust violation and the fact of antitrust impact cannot be established through common proof."); *Bell Atl. Corp. v. AT & T Corp.*, 339 F.3d 294, 302 (5th Cir. 2003) ("[W]here fact of damage cannot be established for every class member through proof common to the class, the need to establish antitrust liability for individual class members defeats Rule 23(b)(3) predominance.").[100] Where the evidence at the class certification stage reveals that a substantial portion of the putative class suffered no impact, certification should be denied. *See, e.g.*, *Sheet Metal Workers*, 2010 WL 285552, at *2 (denying certification because some class members suffered no impact); *Agric. Chems.*, 1995 WL 787538, at *11; *2 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law* § 356d (rev. ed. 1995) ("[T]he fact that some class members may not have been damaged at all generally defeats class certification because the fact of injury, or 'impact,' must be established by common proof."). As this court has noted, it is "immensely difficult to determine classwide economic impact in indirect purchaser actions." *OSB Antitrust Litig.*, 2007 WL 2253425, at *7. That is precisely the case here, even applying Dr. Rausser's flawed assumptions and but-for world hypothetical.

1. Evidence Shows that Many Members of the Proposed Classes Would Not Be Impacted by a Delay in Generic Entry

Here, the evidence shows that substantial numbers of class members would not have been impacted by a delay in generic entry.

[100] *See also Allied Orthopedic Appliances, Inc. v. Tyco Healthcare Group L.P.*, 247 F.R.D. 156 (C.D. Cal. 2007) (denying class certification in an antitrust case as "class certification is precluded where plaintiffs have not shown that the fact of injury element can be proven for all class members with common evidence."); *Schoenbaum v. E.I. DuPont De Nemours & Co.*, 2009 WL 4782082, at *9 (E.D. Mo. Dec. 8, 2009) (denying class certification as "predominance is not satisfied where proof of antitrust impact… calls for an individualized inquiry instead of proof common to the class.").

a. Brand Loyal Consumers Suffered No Impact and Cannot Readily be Ascertained

Plaintiffs concede that brand loyal consumers, whether insured or uninsured, would not have been impacted by a delay in the entry of generic Doryx capsules, because their acquisition price for the brand likely would not have decreased with the generic entry. Despite this concession, Plaintiffs make no adjustment for brand loyal consumers, claiming that (1) they are too few in number to worry about and (2) they can be identified and excluded as necessary during an undefined claims administration process. Dr. Rausser thus does not present a formulaic methodology for identifying and excluding brand loyal consumers from the proposed classes.

Plaintiffs cannot carry their Rule 23(b) burden with such an approach. First, as noted above, "impact" is part of the class certification determination and cannot be deferred to a claims administrator. *See, e.g.*, *Hydrogen Peroxide*, 552 F.3d at 311 ("Importantly, [antitrust impact] is an element of the cause of action; to prevail on the merits, every class member must prove at least some antitrust impact resulting from the alleged violation."); *Bell Atl. Corp.*, 339 F.3d at 302. Courts consequently reject classes where some class members concededly suffered no impact from the allegedly unlawful conduct. In those instances, proof of antitrust impact would require individualized inquiry instead of proof common to the class. *See Kohen v. Pac. Inv. Mgmt. Co.*, 571 F.3d 672, 677 (7th Cir. 2009) (cautioning "that a class action will often include persons who have not been injured by the defendant's conduct," but "if the [class] definition is so broad that it sweeps within it persons who could not have been injured by the defendant's conduct, it is too broad"); *In re High Tech Employees*, 289 F.R.D. 555, 583 (N.D. Cal. 2013) ("The Court is also concerned that Plaintiffs' proposed classes may be defined so broadly as to include large numbers of people who were not necessarily harmed by Defendants' allegedly

unlawful conduct."); *Edwards v. Zenimax Media Inc.*, 2012 WL 4378219, at *5 (D. Colo. Sept. 25, 2012) (class definition was overbroad where it included members "who presumably purchased Oblivion from anyone, anywhere, at any time regardless of whether he or she was ever injured"); *In re Prudential Ins. Co. of Am. SGLI/VGLI Contract Litig.*, 286 F.R.D. 155, 158-59 (D. Mass. 2012) (where there were class members who did not suffer injury and determination of injury would require individualized inquiries, certification was not appropriate). In fact, courts do not hesitate to reject indirect pharmaceutical classes due to the individual issues presented by brand loyal consumers. *See Sheet Metal Workers*, 2010 WL 285552, at *25–26 (certification denied where brand-loyal purchasers could not be identified in a formulaic manner).

Second, Plaintiffs are simply wrong when they label the number of brand loyal consumers as "insignificant." First, as explained below, Dr. Rausser's damages model assumes, *at minimum*, that [redacted] of patients would stay with the brand, *i.e.*, remain brand loyal.[101] This could amount to nearly 70,000 individuals being brand loyalists during the alleged class period.[102] Moreover, even if you take just insured consumers into account, Dr. Cremieux determined that 19% of insured patients in his data set (the same data set Dr. Rausser uses in his supplemental declaration on numerosity) stuck with branded Doryx despite the availability of generic alternatives.[103] This would translate into over *180,500* insured consumers who would not have been impacted by a delay in generic entry.[104] These do not represent insignificant amounts.

[101] [redacted]

[102] *See* Back-Up to Cremieux Decl. ¶ 32 [redacted].

[103] Cremieux Decl. ¶ 30.

[104] Cremieux Decl. ¶ 32 (19% of 950,000 insured patients receiving Doryx).

Finally, Plaintiffs cannot cure this problem by trying to define brand loyalists out of the classes. Some cases have allowed such carve-outs, but only where the generic in question had actually launched, and brand-loyal consumers could be identified. *See, e.g.*, *Terazosin*, 220 F.R.D. at 692; *Relafen*, 221 F.R.D. at 272–73; *Cardizem*, 200 F.R.D. at 343, 347; *Sheet Metal Workers*, 2010 WL 285552, at *6–7 (Wellbutrin SR). No such real-world data exists here because the generic Plaintiffs posit, the generic Doryx *capsule*, never came to market in significant quantities.[105]

b. Patients Receiving Free Samples and/or Using Coupons and Also Purchasing Doryx Without Coupons Suffered No Impact and Cannot Readily be Ascertained

Dr. Rausser agrees that an economic analysis of the but-for world requires, among other things, the consideration of benefits received by the plaintiff from the alleged unlawful activity. As explained by a leading treatise (relied upon by Dr. Rausser):

> "Similarly, the but-for principle requires that the calculated differential between the but-for and actual plaintiff incorporate benefits the plaintiff derived from the violation. By definition, those benefits would not exist in the but-for world. If the quantification of the but-for plaintiff is not adjusted to ensure that the offsetting benefits are accounted for, the differential will be overstated, and the plaintiff will be overcompensated."

See ABA Section of Antitrust Law, *Proving Antitrust Damages: Legal and Economic Issues*, at 61 (2d Ed. 2010) (citing *L.A. Mem'l Coliseum Comm'n v. NFL*, 791 F2d 1356, 1366-73 (9th Cir. 1986)). Thus, as Dr. Cremieux explained, "[a]n economic analysis of individual injury requires an analysis of all impacts, not just those that harm the individual."[106]

Dr. Rausser's analysis ignores this basic requirement. Instead of looking at all of the transactions that affected consumers in devising a formulaic approach to evaluating whether

[105] Generic *tablets* entered the market in January 2011, as discussed in the Factual Appendix, but Plaintiffs do not use the tablets experience as a model for its but-for world.

[106] Surrebuttal Declaration of Pierre-Yvex Cremieux, July 11, 2013 (Ex. 1) ¶ 29.

consumers suffered antitrust impact, Dr. Rausser considered the proposed class to be defined in terms of "the intersection between people and the transaction."[107] He thus excluded as not part of the class (and hence not part of his analysis) (1) all free samples issued by Warner Chilcott,[108] and (2) all coupons transactions.[109] He does this despite having conceded elsewhere that ignoring such factors would overstate damages.[110] As Dr. Cremieux explains, by selectively excluding transactions for which proposed class members were better off in the actual world, Dr. Rausser "does not address the question of whether there is common impact, but rather whether there is common impact for the subset of Class Members' transactions that Plaintiffs choose to consider."[111] Having addressed the wrong question, Dr. Rausser's "answer" can be ignored.

To illustrate the flaw in Dr. Rausser's approach, Dr. Cremieux provides the example of a consumer who purchased Doryx three times, the first two times with a consumer coupon that reduced her co-pay to zero, and the last time without a coupon, resulting in a $25 co-pay.[112] In total, this consumer paid $25 for her three Doryx prescriptions in the actual world. In Dr. Rausser's but-for world, this consumer instead would have purchased three prescriptions of generic Doryx, paying in each instance a generic co-pay of $10, resulting in a total payment of $30 for the three prescriptions. Although this consumer would suffer no impact—she was better

[107] Rausser Merits Dep. Tr. (Ex. 109) 352–53 [redacted] Dr. Rausser acknowledged a similar approach in *In re Skelaxin*, which the court considered to be evidence that individual inquiry was necessary, and thus, denied certification of an end payer class. *In re Skelaxin (Metaxalone) Antitrust Litigation*, 1:12-md-02343, Dkt. No. 508, at 23–24 (E.D. Ten. Jan. 30, 2014).

[108] Rausser Rebuttal Report ¶ 114.

[109] Plaintiffs' Amended Motion at 3–4.

[110] Rausser Nexium Decl. ¶ 39 (Ex. 103) ("Because generic drug manufacturers seldom offer incentives of this type, any analysis that fails to factor in the effect of consumer coupons and rebates will provide a deceptive picture of the relative costs of" the drug products at issue.).

[111] Cremieux Surrebuttal ¶ 29.

[112] Cremieux Merits Rep. ¶ 98, Ex. 12.

off by $5 in the actual world—Dr. Rausser not only would include her in the class, but also would provide her $15 in damages.[113]

This flaw in Dr. Rausser's approach is substantial. Tens and perhaps hundreds of thousands of patients used coupons to purchaser Doryx.[114] Many may have purchased Doryx without a coupon as well, which would mean that they would remain in Plaintiffs' proposed class even with the revised carve-out. Dr. Rausser's exclusion of sample transactions creates a similar result. Patients benefited from millions of free samples of Doryx tablets, a benefit that, like coupons, lowered real-world costs. Dr. Rausser has agreed with this proposition previously and provides no basis for taking a different approach and ignoring samples altogether in this case.[115] By focusing on "transactions" and not consumers, Dr. Rausser overstates damages and fails to exclude substantial numbers of consumers who were not impacted.[116]

c. Many Insured Consumers Suffered No Impact—Insurance Caps and Formulary Placement Require Individualized Inquiry to Determine Impact

Many insurance plans offer prescription drug coverage whereby the consumer in some instances has no out of pocket expenses for a prescription, brand or generic. For example, some plans set deductibles or levels of out of pocket expenses that, once reached, insulate the insured consumer from any further costs for prescription drugs. Consumers who have reached such maximum amounts would suffer no injury due to a delay in generic entry.[117] The OptumHealth

[113] *See supra* Part II.B.1 (discussion of similar example for uninsured consumers).

[114] *See* Cremieux Merits Rep. ¶ 65 ("As I noted in my class certification report, consumers used nearly 500,000 cards for almost a million total redemptions.").

[115] Rausser Nexium Decl. (Ex. 103) ¶ 166; Cremieux Merits Rep. ¶ 101.

[116] *Id.* at ¶ 99.

[117] Cremieux Decl. ¶ 39 (discussing examples from different IBEW chapters).

data[118] shows that over 2,000 patients would not be injured in the but-for world because they obtain their Doryx prescriptions at no cost, possibly because they had met their deductible out-of-pocket limit.[119] Data from the Kaiser Family Foundation, a source used by Dr. Rausser, likewise suggests that a substantial number of insured consumers had the benefit of such caps.[120] Moreover, the only way to identify these individuals would be first to identify the plans that offered such coverage for each year in the damage period. Then, for plans with deductibles, to determine whether and when—in each year—each individual patient under such plan reached her out of pocket maximum cost / deductible.[121] Dr. Rausser briefly addresses these issues from the point of view of the third party payer and concludes that none of these "factors would materially change [his] analysis,[122] but fails to address these issues with respect to consumers, let alone provide a formulaic way for identifying these individuals.

Dr. Rausser also fails to consider plans with formularies like the one used by IBEW.

[redacted]

[118] OptumHealth data is a "widely used source of health economics data concerning individual patent prescription histories." Cremieux Decl ¶ 12. The OptumHealth data set includes prescription reimbursement claims "for over 16.4 million individuals covered by 69 self-insured Fortune 500 companies" adjudicated for a 12 year period (January 1999 through March 2012). "The data reports the amount paid by the plan, the amount paid by the consumer, and the amount paid, if any, by other insurers." Cremieux Decl. ¶ 13. The data contains more than 150,000 prescription records for Doryx (capsules and tablets) and more than 1,600 prescription records for the 75 and 100 mg capsule and tablet products sold by Sandoz and Mylan, respectively. Cremieux Decl. ¶ 14.

[119] *Id.*

[120] *Id.* at ¶ 39; Kaiser Surveys 2012, (Ex. 147) at 149 (stating that "11% of covered workers with coverage for prescription drugs are in plans with a separate prescription drug annual out-of-pocket limit").

[121] Cremieux Decl. ¶ 39.

[122] Rausser Merits Rep. ¶ 128. Even as to TPPs, Rausser errs. *See infra* Part III.D.1.d.

[redacted]

[redacted]

Furthermore, Dr. Rausser does not consider the very realistic possibility that, due to Warner Chilcott's withdrawal of promotion of Doryx capsules after generic entry, which Dr. Rausser concedes was legal and could have occurred,[126] consumers would have been switched to a different generic (such as immediate-release doxycycline hyclate) in his but-for world. Warner Chilcott credited its ability to retain a substantial share after Mylan's generic entry of the 150 mg tablet through heavy detailing and promotion.[127] Were it not for this detailing, there is a substantial chance consumers would have switched to a non-Doryx product. This is supported by switching data reviewed by Dr. Cremieux and Dr. Addanki, which show that 12 to 13% of patients switched from Doryx to a non-Doryx generic after generic entry.[128]

d. Third Party Payers (TPPs)

The TPP portion of the proposed class fares no better than the consumer segments with respect to assessing impact on a formulaic, classwide basis. The problems in this regard are all ones that Dr. Rausser himself acknowledged in his work in the Nexium litigation. Setting aside the fundamental question of ascertaining which TPPs would be in the class given the complex

[125] Cremieux Decl. ¶ 36.

[126] Rausser Merits Dep. Tr. at 62:22–63:3.

[127] Q1 2013 Warner Chilcott Earnings Call Transcript at 4 (Ex. 59) ("Despite [the launch of a generic product in May 2012 by Mylan], IMS Health data shows prescription volumes for Doryx® 150mg tablets sold by Warner Chilcott . . . are not following a typical generic substitution curve and have only fallen approximately 35% since the entry of generic competition and stabili[z]ed across June, July and August. Over this period Warner Chilcott have maintained their national Doryx® sales force and customer loyalty card.").

[128] Addanki Rep. ¶ 116, Attachment 9b (analysis of switching data); *see also* Cremieux Merits Rep. ¶ 67–68, 70.

web of risk-sharing that exists among TPPs and plan sponsors, individualized analysis would be required to assess whether any particular TPP would have been harmed by a delay in generic entry.

To determine whether any TPP was impacted, as Dr. Rausser has admitted, one must first understand the nature of the financial responsibility being shouldered by the TPP, the level of manufacturer rebates the TPP is receiving, directly or indirectly, with respect to Doryx, the co-payment (or other cost sharing) imposed on insured patients for Doryx under the relevant insurance plan, the benefits of free samples received by plan members, and how all of these many attributes may vary in the but-for world.[129] Dr. Rausser has proposed no classwide methodology for evaluating any of these factors.

i. Each TPP's Risk Sharing Arrangements Would Have to be Assessed to Determine Impact

Identifying whether and to what extent a TPP is "at risk" for a pharmacy benefit is central to evaluating impact, but Dr. Rausser proposes no methodology for undertaking this inquiry. [redacted] The nature and extent of such arrangements vary greatly, and can have tremendous implications for whether a TPP has been impacted by a delay in generic entry. Plaintiff concedes that "fully insured health plans" that is, plans that transferred "100% of the plan's reimbursement obligations" to another TPP through an insurance contract, would not have been impacted and thus must be excluded from the class.[131] But Dr. Rausser proposes no formulaic methodology for identifying such

[129] Rausser Nexium Decl. (Ex. 103) ¶ 46.
[130] Rausser Class Cert. Dep. Tr. 61:18–62:5.
[131] Plaintiffs' Amended Brief at 2–4.

plans, [redacted] one would have to evaluate the TPP's expenditures for Doryx net of all rebates received by the TPP for Doryx. Particularly when the rebates are factored in, the TPP may be better off reimbursing for Doryx rather than generic Doryx, because there likely will be no rebate from the generic manufacturer.[135] When this complexity is multiplied by the number of plans and the number of years at issue in this case, it is not possible to conclude, based on average reimbursement rates that each TPP in the class would suffer injury associated with the alleged unlawful conduct in this case.

Dr. Rausser has only considered such risk sharing in the context of Medicare Part D. Dr. Rausser apparently assumes that risks associated with Medicare Part D prescriptions are borne by private TPPs. The federal government, however, bears the majority of the risk for Medicare Part D prescriptions.[136] Dr. Rausser argues that Medicare Part D plans should remain in the class because it is the private plan that is responsible for paying for the drug, regardless of the fact that

[132] Rausser Class Cert. Dep. Tr. 63:13–64:14.
[133] *Id.* at 61:18–62:24.
[134] *Id.* 62:6–62:24.
[135] Cremieux Decl. ¶¶ 59–60.
[136] Cremieux Decl. ¶ 61.

the government reimburses the plan for these payments,[137] and thus the ultimate risk is borne by the government. Rausser's own analysis has estimated that these reimbursements amount to 1% of Doryx prescriptions, but has failed to propose a methodology of identifying these reimbursements on the state level.[138]

ii. Many TPPs Suffered No Impact because the Alleged Savings from Generic Doryx Would Have Been Offset by the Loss of Manufacturer Rebates and the Reduction in Cost Sharing from Insured Patients

The cost to TPPs varies based on the reimbursement rate paid to pharmacies, the rebates received from the drug manufacturer, the amount of cost sharing with the insured consumer (*e.g.*, the insured consumer's co-pay), and the use of samples (which reduces overall cost of therapy for the insured patient).[139] Of particular significance are manufacturer rebates. Warner Chilcott paid substantial rebates to TPPs to ensure that Doryx would be included on the TPPs' formulary and available as a covered drug under the TPPs' pharmacy benefit plans.[140] Generic manufacturers, by contrast, typically do not pay rebates to TPPs, and TPPs in the but-for world would not receive the benefit of such rebates from manufacturers of generic Doryx. A similar dynamic operates with respect to insured patients. When an insured patient switches to a generic and incurs a lower co-pay, the proportion of overall cost to the TPP (if not the total cost) increases. As Dr. Rausser conceded in *Nexium*, "[t]ypically, the greater the individual consumer's co-pay, the less the effective cost to the third party payer."[141]

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[137] Rausser Rebuttal Decl. (Ex. 103) ¶ 90.

[138] *Id.*

[139] Rausser Nexium Decl. (Ex. 103) ¶ 44-45.

[140] Cremieux Decl. ¶ 109; [redacted]

[141] Rausser Nexium Decl. (Ex. 103) ¶ 80; Rausser Decl. ¶ 111; Rausser Merits Rep. ¶ 124.

These factors are particularly important where, as here, the difference between the brand and generic price was not substantial. As Dr. Rausser has explained, if the difference between the brand and generic co-pays and the loss of the manufacturer rebate is greater than the difference between the brand and generic reimbursement price borne by the TPP, then the TPP is not harmed.[142] *See In re K-Dur*, 2008 WL 2660723, at *11 (finding no impact in part because "the difference between the price of branded K-Dur and the generic alternative may be less than the difference between the higher co-pay a TPP receives for branded K-Dur and the lower co-pay the TPP receives for the generic alternative"). In fact, Dr. Cremieux's analysis of OptumHealth data identified scores of examples where TPPs paid roughly the same or less for Doryx 100 mg tablets than they did for its generic counterpart.[143] This analysis did not even consider other factors (such as the effect of samples) which would have lowered the net effective cost of Doryx (but not the generic) even further.[144]

Dr. Rausser eschews this real-world data in favor of his assumption that the but-for world would be completely genericized by the beginning of the class period.[145] This allows him to argue that the spreads between the prices for Doryx and generic Doryx in his but-for world would have been large enough to make up for the lost rebates from Warner Chilcott and the reduced co-payments from insured patients. But, as discussed below, his assumptions on generic entry are totally unsupported.

Aware that this issue is a problem even with his (unsupported) but-for world assumptions, Dr. Rausser performs a slanted "sensitivity analysis" which he claims establishes

[142] The first AB-rated generic to enter the market typically prices its product at a relatively small discount to the brand until other generics enter the market. Cremieux Decl. ¶ 74.

[143] Cremieux Decl. ¶ 74.

[144] Cremieux Decl. ¶ 68.

[145] Rausser Merits Rep. ¶ 111; Rausser Rebuttal Rep. ¶ 101.

that the rebate / co-pay effects would not lead any TPP to be worse off reimbursing for generic Doryx.[146] This analysis provides no cover for Dr. Rausser's flawed conclusions.

First, Dr. Rausser's sensitivity analysis only focuses on two factors—rebates and co-pays—that can influence a TPP's costs. But, as Dr. Cremieux's analysis shows, several other factors affect whether a TPP was impacted.[147] For example, timing is important, because even under Dr. Rausser's analysis, damages to TPPs would be negative during certain periods of time, and plans that only reimbursed Doryx in those periods would not be injured.[148] These are not "anomalies" as Dr. Rausser suggests, but instead, were observed by Dr. Cremieux for multiple plans in the OptumHealth data.[149] Moreover, several other factors also impact the cost to TPPs, such as free samples from Warner Chilcott, deductibles, prescription benefit maximums, and the use of preferred pharmacy networks.[150] Specifically, in a but-for world without samples, TPPs would instead have to reimburse for purchases of generic Doryx, where in the actual world, patients would have used free samples and the TPP would have made no reimbursement.[151] Also, instead of addressing remaining factors such as deductibles and prescription benefit maximums, Dr. Rausser argues that he does not need to consider them because he believes they would have "little or no bearing on common impact."[152] However, Dr. Cremieux correctly points out that "even a small number of prescriptions paid for by consumers who are under the

[146] Rausser Merits Rep. ¶ 127.
[147] Cremieux Decl. ¶ 63–69; Cremieux Surrebuttal ¶¶ 24–26.
[148] Cremieux ¶¶ 65–67.
[149] *Id.* ¶ 66.
[150] Cremieux Surrebuttal ¶¶ 24–25.
[151] Cremieux Merits Rep. ¶ 102.
[152] Rausser Merits Rep. ¶128.

deductible can have a significant effect on the number of plans that are impacted because the number of Doryx prescriptions purchased by plan members may be quite small."[153]

Second, even when limited to an examination of only rebates and co-pays (despite being improper), Dr. Rausser's own sensitivity analysis shows that many TPPs would not be impacted if other assumptions in Dr. Rausser's model are replaced with reasonable alternatives. For example, Dr. Cremieux evaluated Dr. Rausser's model after replacing his generic-to-brand price ratios with an alternative set of ratios based on the academic literature in economics. Even when Dr. Rausser's extreme values for copays and rebates were used, Dr. Cremieux found that 25% of the companies in the OptumHealth data that reimbursed for at least one Doryx prescription over the period September 2008 through Q1 2012 were unharmed.[154]

At a minimum, Dr. Cremieux's empirical analysis shows that Dr. Rausser's sensitivity analysis does not eliminate the need for an individualized inquiry of impact because changing the assumptions regarding co-pays yields a different set of uninjured TPPs, a point Dr. Rausser seems to concede.[155] Dr. Rausser's sensitivity analysis highlights the fact that an individualized inquiry would be required to assess the impact of the alleged delay on individual TPPs.

iii. Brand Loyal Consumers Lead to No Impact to TPPs

As discussed above, brand loyal insured consumers suffered no injury. Similarly, TPPs suffered no injury when reimbursing prescriptions filled by brand loyal consumers, because the cost in the hypothetical but-for world would be the same as (or potentially higher than) the cost in the actual world.[156] [redacted] Absent evidence that a TPP did in fact

[153] Cremieux Surrebuttal ¶ 26.
[154] Cremieux Surrebuttal ¶ 22.
[155] Cremieux Decl. ¶ 67; Rausser Class Cert. Dep. Tr. (Ex. 117) at 218:7–220:1.
[156] Cremieux Decl. ¶ 71.

reimburse for generic Doryx in the actual world, there is no basis to infer that the TPP would have reimbursed for the generic (and thus potentially suffered injury) in the hypothetical but-for world.[157] *See In re Flonase*, 284 F.R.D. at 216 (excluding TPPs that reimbursed brand but never reimbursed for generic); *In re Wellbutrin XL Antitrust Litigation*, 282 F.R.D. at 126 (same).

Here, the data show that a substantial number of TPPs had only brand loyal members. As Dr. Cremieux explains, the real-world data show that 22% of TPPs in the OptumHealth dataset *never reimbursed a single generic Doryx prescription* through the first quarter of 2012, despite the fact that Mylan launched its 75/100 mg tablets in January 2011.[158] Further, the real-world data also show TPPs and pharmacies did not push patients to the Mylan 75/100 mg tablets, even though it was AB-rated and thus fully substitutable for Doryx tablets of the same strength, and TPPs and pharmacies easily could have driven utilization to the Mylan tablets.[159] This is not at all surprising given that multiple documents produced by third parties in this case demonstrate that, if anything, TPPs pushed patients to non-generic Doryx products.[160] These facts refute Dr. Rausser's assertion that generic erosion would be substantially greater in the "but-for" world and show instead that many TPPs likely would suffer no impact.

[157] *Id.* ¶ 72.

[158] Cremieux Decl. ¶ 72; *see also id.* ¶ 73 (hundreds of TPPs nationwide likely only had brand loyal users).

[159] Dr. Rausser admits that TPPs have it within their power to drive utilization to generic alternatives. Rausser Class Cert. Dep. Tr. (Ex. 117) 210:15–211:15).

[160] *See, e.g.* [redacted]

iv. TPPs not Impacted Where They Pass on Price Increases Through Premiums

Plaintiffs assert claims under Florida, Nevada, and West Virginia state laws. Florida recognizes the "pass-on" defense to an overcharge claim, that is, that a plaintiff was not harmed if it was able to pass on all or part of an overcharge to its customers downstream. *See, e.g., In re TFT-LCD (Flat Panel) Antitrust Litig.*, 2013 WL 1010389, at *2 (N.D. Cal. Feb. 6, 2013) (recognizing that no Florida case law precludes the pass-on defense under the FDUTPA). Nevada and West Virginia have legislation repealing the indirect purchaser rule, with no limitation on pass-on defenses. *See* NEV. REV. STAT. 589A. 210(2); W.VA. CODE § 142-9-2.

Like any insurance company, TPPs generally pass on their costs in the form of premiums.[161] TPPs usually do this by setting premiums that are expected to be sufficient to cover future medical costs reimbursable under the terms of the plan. Insurers often predict likely future medical costs for plan members by analyzing actual costs incurred in the past (often referred to as "experience rating").[162] To the extent TPPs perceived their costs increasing because of a delay in generic entry, they would have raised their premiums for future periods, and thus passed on any alleged overcharge, resulting in no harm to the TPPs.[163] *See Ironworkers Local Union v. AstraZeneca Pharm.*, 634 F.3d 1352, 1364–65 (11th Cir. 2011) (discussing premium setting process); *Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris, Inc.*, 138 F. Supp. 2d 357, 360 (E.D.N.Y. 2001) ("Insurance companies . . . are financial intermediaries that set their rates so as to cover all anticipated claim costs. . . . [A]s costs increase, from whatever source, insurers can pass the majority of these costs onto the insurance buyers through

[161] Expert Report of Bruce A. Strombom, (Ex. 1) August 9, 2013 ¶ 15.

[162] Cremieux Decl. ¶ 70; Cremieux Merits Rep. ¶ 103; Rebuttal Expert Report of Bruce A. Strombom, December 23, 2013 (Ex. 1) ¶ 6 ("Strombom Rebuttal").

[163] *Id.*

subsequent premium increases."); *Int'l Bhd. of Teamsters v. Philip Morris Inc.*, 196 F.3d 818, 824 (7th Cir. 1999) (TPPs "are just financial intermediaries"). Individualized inquiry would be needed, then, for each of the proposed classes, as to whether the TPPs passed on all or part of any assumed overpayment for Doryx.

There can be little dispute that pass on is a relevant inquiry for class certification because the extent to which TPPs passed on the alleged overcharge is essential to determining whether they were impacted by Defendants' allegedly anticompetitive conduct.[164] Assessing pass-on is an inherently individualized undertaking in most instances. *See, e.g.*, *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 741 (1977) (discussing complexities of assessing the pass-through of overcharges in a chain of distribution). Here, Dr. Rausser claims there is no relevant pass on and thus dismisses the need for such an analysis. Dr. Rausser's simplistic approach is incorrect and ignores the substantial pass on that occurs from TPPs to policyholders in the form of premium increases and other financial adjustments.

First, Dr. Rausser's initial argument that Doryx purchases and health insurance premium payments are part of two separate distribution chains, and thus that consumers are not actually "purchasing" Doryx when purchasing health insurance but are purchasing the right to be reimbursed, is not correct.[165] As Defendants' expert, Dr. Strombom, an economist who has worked extensively on health care and insurance industry issues, explains, "the important point . . . is that the TPP, the [consumer], and the employer share responsibility for paying for the [consumer's] use of Doryx."[166] Hence, changes in the cost of Doryx may affect each party's ultimate payments. This is the essence of a pass-on situation.

[164] Strombom Rebuttal ¶ 5–6.
[165] *Id.* at 5–6.
[166] Strombom Rebuttal ¶ 18.

Second, Dr. Rausser's argument that the correlation between the healthcare costs incurred by a TPP and the premiums it charges does not imply pass-on is similarly flawed. Stated differently, he essentially argues that there is no empirical evidence that the overcharges for a single drug would result in an increase in premiums.[167] But this argument ignores basic economic principles and the evidence presented by Dr. Strombom. "Ignoring a cost simply because it is a small percentage of overall health care costs makes no economic sense because there are many such costs, and therefore ignoring costs below a certain threshold will cause the plan to ignore a substantial portion of its aggregate costs."[168] [redacted] TPPs thus will rationally consider all relevant costs, including relatively small costs, in making premium setting decisions. Moreover, the evidence shows a direct, strong, and statistically significant correlation between health care costs, including the cost of prescription drugs, incurred by TPPs and the premiums that they charge.[170] Simply stated, TPPs consider their aggregate costs in setting premiums, such

[167] Rausser Pass-On Rep. at 11–12.

[168] Strombom Rep. ¶ 34.

[169] Strombom Rep. ¶ 34.

[170] Dr. Strombom analyzed information from various sources and observed an overwhelmingly positive correlation between healthcare expenditures paid for by insurance companies and the premiums charged by those insurance companies. *See, e.g.*, Strombom Rep. ¶ 23, Exhibit 2 (observing a positive correlation of 0.81 between the annual growth rates of private insurance healthcare costs and private insurance premiums for the period 2001 to 2011 and a correlation of 0.95 between premium expenditures and total personal healthcare costs); Strombom Rebuttal ¶ 28, 30 (10-K data from ten U.S. health insurers indicated a 0.99 correlation between health care costs and premium revenues and percentage change between both variables); ¶ 31 (data from 240 health insurers required to report premium and health care cost information under the Affordable Care Act indicated a 0.999 correlation coefficient between costs and premiums).

aggregate costs would include those for all prescription drugs (including Doryx), and there is no reason why a TPP would ignore an increase in the cost of a drug in this process.[171]

Third, Dr. Rausser argues that past healthcare costs are merely pieces of information used to estimate future costs, and that these costs are not passed on to premiums.[172] Dr. Rausser also gets this wrong.[173] As noted, TPPs typically use an "experience rating" process that incorporates actual past costs in order to determine expected future costs, so that they can set premiums that will likely cover those future costs.[174] "Thus, costs in the current year serve as the bases for setting premiums for the plan in subsequent years."[175] [redacted] This process strongly implies that higher costs are passed-on to plan members in the form of higher premiums.

Moreover, insurers use other techniques to adjust costs with policyholders. Some insurers may use a "deficit recovery charge" to increase future premiums on accounts that have suffered past losses and thus pass on to a specific policy holder, at least in part, certain higher costs. Other insurers may use "retrospective experience ratings" which allow the insurer to

[171] Strombom Rebuttal ¶ 33.
[172] Rausser Pass-On Rep. at 12–13; Strombom Rebuttal ¶ 37.
[173] Strombom Rebuttal ¶ 38
[174] Cremieux Decl. ¶ 70; Cremieux Merits Report ¶ 103; Strombom Rebuttal ¶ 6.
[175] Strombom Rebuttal ¶ 38.
[176] Strombom Rep. ¶ 27; [redacted]

reflect the experience of the policy holder in a particular year, whether positive or negative, in the premium for that year through an after the fact adjustment.[177]

Lastly, Dr. Rausser simply ignores the regulatory environment in which health insurance premiums are set, which in certain instances requires health insurers to pass on cost increases through an increase in premiums. As explained by Dr. Strombom, the Medical Loss Ratio[178] ("MLR") rules enacted by the Affordable Care Act ("ACA") require "an insurer operating at or below the minimum MLR [to] pass on any cost increases (or overcharges) in the form of lower rebates to policy holders."[179] Data reported by insurers under the ACA and analyzed by Dr. Strombom show that these premium adjustments occurred frequently.[180]

v. The Timing of Each Reimbursement and the Provisions of Each Health Plan Create No-Impact Situations

Even where plan members may purchase a generic Doryx product in the hypothetical but-for world, TPPs may require patients to meet a deductible limit before the TPP will reimburse any portion of the cost of a prescription. If a plan member has not met his or her deductible—or if the deductible applied only to brand name drugs, with the TPP sharing in some of the cost of generic prescriptions, the TPP would suffer no impact.[181]

* * *

[177] Strombom Rebuttal ¶42.

[178] A health insurer's "Medical Loss Ratio" is the ratio of an insurer's spending on medical benefits to the total amount of health insurance premiums it collects. Under the ACA, "If an insurer fails to achieve the minimum MLR in a market within a state, it must rebate to policyholders the amount of the premium sufficient to raise the MLR to the minimum level." Strombom Rebuttal ¶ 34.

[179] Strombom Rebuttal ¶ 35.

[180] *Id*. at ¶ 36 (In 2011, around $123 million in rebates was paid to 1.2 million consumers in Florida and more than $4 million was paid to consumers in Nevada. "These payments benefitted about 46,000 consumers in 2011 and about 88,000 consumers in 2012. Consequently, the data indicate a considerable incidence of health insurers passing on cost increases into premiums in accordance with government regulations.").

[181] Cremieux Decl. ¶ 76.

Critically, as demonstrated above, this is not a case where only a "few" class members were uninjured, as Plaintiffs attempt to allege. IPP Amended Brief at 34 (citing *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 227 (E.D. Pa. 2012)). Rather, in this case, Plaintiffs have failed to show that a substantial number of potential class members were impacted. Indeed, Defendants have shown the contrary. As this court has noted, where the evidence shows that many members of the proposed class would not have paid increased prices, "this suggests that plaintiffs will have to prove economic impact customer by customer, exactly what the [Third Circuit] condemned [in *Linerboard*]." *OSB Antitrust Litig.*, 2007 WL 2253425, at *21. That is exactly the case here, and thus, certification should fail.

2. Dr. Rausser's Generic Entry Assumptions Contradict the Facts

In addition to his unsupported assumptions regarding the Doryx tablet products, Dr. Rausser also reaches unsupported conclusions regarding the entry of generic Doryx capsules.[182] Dr. Rausser originally (and incorrectly) assumed that multiple generic manufacturers would have been ready, willing, and able to launch generic Doryx capsules in July 2006. When he actually calculated damages in his merits report, Dr. Rausser switched to a different assumption, presumably because he recognized his original one was untenable. [redacted] Despite changing this important assumption, Dr. Rausser did not revise his impact analysis. Instead, he simply concluded that the market would have been "genericized" by the start of the class period in 2008.

[182] Cremieux Decl. ¶¶ 86–91.

[183] Rausser Merits Rep. ¶ 90, 95.

Dr. Rausser's new assumptions are contradicted by the evidence and thus cannot be used to carry Plaintiffs' burden to show classwide impact. [redacted][4] Thus, any so-called "opinions" he has regarding when any generic company would have been able to receive FDA approval, or whether any generic company could have addressed any manufacturing or development concerns, are inadmissible. *In re Paoli Railroad Yard PCB Litig.*, 35 F.3d 717, 767 (3d Cir. 1994) (upholding district court's determination that expert's testimony on plaintiff's skin condition was inadmissible, where the expert "admitted she was not an expert in dermatology, and she demonstrated little knowledge about [a specific skin condition]."); *Kent v. Howell Elec. Motors*, No. CIV. A. 96-7221, 1999 WL 517106, at *5 (E.D. Pa. July 20, 1999) (expert testimony on adequacy of warnings not admissible where expert "admits he is not an expert in warnings design.")

a. [redacted]

[184] Rausser Merits Dep. Tr. (Ex. 109) at 45:3–9.

[185] [redacted]

[186] [redacted]

[redacted]

b. No Authorized Generic

[redacted]

[redacted]

[redacted]

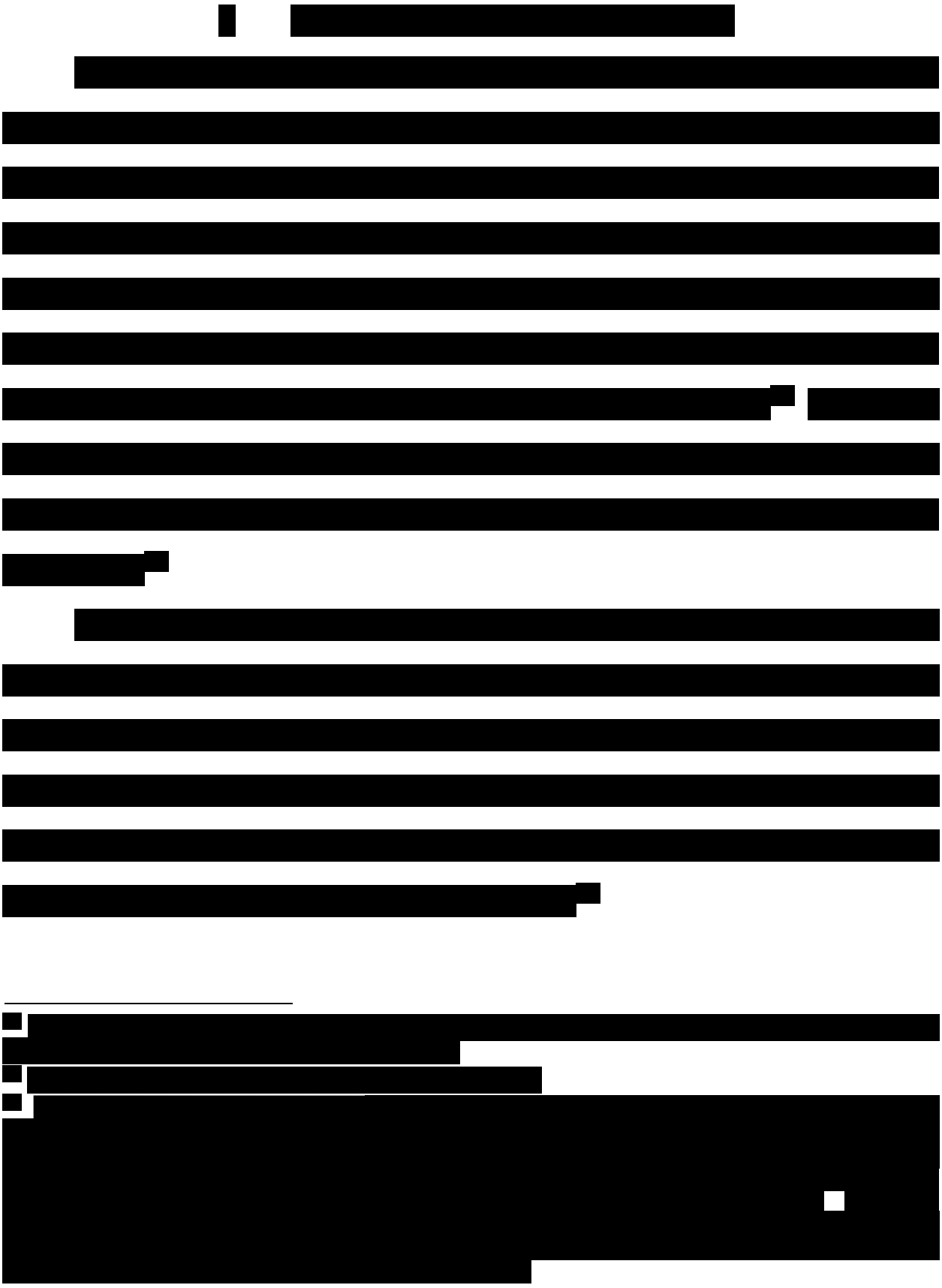
Again, the facts rebut Dr. Rausser's flawed assumption. In the actual world, Mayne waited until six months after it acquired Metrics, Inc., a U.S.-based contract services provider with Doryx-relevant specialty pelleting technology and manufacturing services, before launching its authorized generic versions of Doryx 75 and 100 mg tablets in July 2013.[193] [redacted] Mayne waited another 18 months, until well after it had acquired Metrics, to actually undertake the launch.[194] [redacted]

[192] Rausser Merits Rep. ¶ 90.

[193] Mayne Pharma Launches Generic Doyxcycline Hyclate Delayed-Release Tablets in the US, Jul. 9, 2013, *available at* http://www.maynepharma.com/download.cfm?downloadfile; Cremieux Merits Rep. ¶ 81.

[194] Mayne Pharma Announces Acquisition of Metrics, Inc., Oct. 3, 2012, *available at* http://www.metricsinc.com/metrics-to-be-acquired-by-mayne-pharma/; Controlled Release Delivery Systems, Metrics, Inc., available at http://www.metricsinc.com/service/specialty-technologies/#tab2. As Mayne's CEO, Scott Richards, explained "We are very excited about the launch of these products which will be the first revenue synergies to materialize from the Metrics, Inc. acquisition completed in November 2012." Mayne Pharma Launches Generic Doyxcycline Hyclate Delayed-Release Tablets in the US, Jul. 9, 2013, *available at* http://www.maynepharma.com/download.cfm?downloadfile; Cremieux Merits Rep. ¶ 82.

[redacted]



[redacted]

[redacted]

Indeed, [redacted] despite having almost two decades of patent-free freedom to do so. [redacted] Again, Plaintiff has the burden of establishing the reasonableness of its assertions, and unsupported assumptions that are contrary to known facts do not do so. *See*, *e.g.*, *Comcast*, 133 S. Ct. at 1438–39.

E. Individual Issues Predominate with Respect to Damages

1. Plaintiffs' Model for Calculating Aggregate Damages is Flawed

As noted above, *Comcast* puts a spotlight on analyzing at the class certification stage the propriety of class plaintiffs' proposed damages methodology. 133 S. Ct. at 1433. Here, Dr. Rausser's proposed methodology—which takes average branded tablet prices, compares them to assumed average prices for generic capsules and applies an assumed generic penetration rate and

[redacted]

[206] Illum Rep. ¶ 133.

assumed generic prices—is rife with problems.

First, in addition to depending entirely on unfounded assumptions about Warner Chilcott's product launches and generic capsule entry dates, Dr. Rausser's damage model uses a generic penetration rate [redacted] But, Dr. Rausser cannot explain why the [redacted] projection is appropriate, given that the actual penetration rate (and associated price erosion) was substantially lower in the actual world, when generic Doryx products eventually entered the market.[209] In short, Dr. Rausser's reliance on a single questionable analysis [redacted] for one assumption that was based on an entirely different market situation is improper.[210] The same criticism applies to Dr. Rausser's use of a 2011 [redacted] projection. Dr. Cremieux showed that by simply replacing Dr. Rausser's generic price assumptions from that projection with another forecast, and keeping all other assumptions the same, Dr. Rausser's damages estimate is reduced by 27 percent.[211] Generally speaking, Dr. Rausser's reliance on these two projections, without any effort to explain why these projections provide useful approximations for a relevant but-for

[207] Dr. Rausser originally relied on inapposite academic articles for his generic price and penetration assumptions. Rausser Decl. ¶¶ 124–25. He abandoned that approach when it came time to actually calculate damages. *See* Rausser Merits Rep. ¶¶ 144–47.

[208] *See* Cremieux Merits Rep. ¶ 84. [redacted]

[209] Cremeiux Merits Rep. ¶ 86.

[210] *See* Cremieux Merits Rep. ¶¶ 84–87.

[211] *Id.* ¶ 88.

world, is improper and leads to a speculative damages calculation.[212]

Second, Dr. Rausser assumes that total combined brand and generic Doryx sales would have been the same or greater in the but-for world as they were in the actual world.[213] However, Dr. Rausser admits that Warner Chilcott supported Doryx with substantial sales and marketing efforts, [redacted] and that these efforts would not have been undertaken in the but-for world he assumes (generic competition without Warner Chilcott follow-on branded products).[214] The inevitable withdrawal of promotion in the but-for world would mean *reduced* volume for the "molecule," rather than the steady volume Dr. Rausser assumes. Indeed, Dr. Rausser's own data shows a substantial reduction in sales for Doryx 150 mg tablets [redacted] thus confirming the volume shrinkage when promotion is withdrawn.[215] Dr. Rausser argues that the decrease in price and movement of generic Doryx to preferred status on formularies would have increased sales of doxycycline hyclate delayed release in the but-for world.[216] Dr. Rausser does not provide any support for this assessment and fails to adequately consider the effect of marketing activities such as sampling, couponing and increasing the size of the sales force on the sales of Doryx[217] and the high levels of switching between doxycycline hyclate delayed release and other forms of generic doxycycline.[218]

Moreover, Dr. Rausser's support for his proposition that the total volume would increase,

[212] *See* Cremieux Merits Rep. ¶¶ 89.

[213] Rausser Decl. ¶ 122; Rausser Merits Rep. ¶¶ 149, 154.

[redacted]

[215] Rausser Decl. fig. 4.

[216] Rausser Rebuttal Rep. ¶ 107.

[217] Cremieux Merits Rep. ¶ 67.

[218] *See* Addanki Rep. ¶ 116, Attachment 9b (analysis of switching data). Dr. Rausser admits that 90% of Doryx patients that switched to other forms of doxycycline switched to generic immediate-release. Rausser Rebuttal Rep. ¶ 110.

or at minimum remain the same, is unpersuasive. The single economics study (a working paper that was subsequently published) he cites finds "ambiguous changes in total market quantity" with patent expiration for advertised products.[219] And Dr. Rausser mischaracterizes Dr. Addanki's report, which clearly rebuts Dr. Rausser's assumption: "When advertising, promotion, and other demand-building activities cease, the entire demand curve will, in effect shift inwards. . . . Even at the reduced price charged by the generic firm, there may be little or no increase in the total quantity demanded of the branded drug (and its generic counterpart). Indeed, quantity may even decline."[220]

Thus, Dr. Rausser's total damage estimate is overstated by the degree that volume would have decreased in the but-for world.

Third, Dr. Rausser's use of *average* prices (for both branded tablets and generic capsules) masks individual issues.[221] As Dr. Cremieux showed using state-level prescription data, the prices actually paid by patients in Nevada and Florida varied substantially, and those price variations were not captured by nationwide average data used by Dr. Rausser.[222] In his reply declaration, Dr. Rausser used OptumHealth data to show prices paid in different states *by plan*,[223] and he concludes that there is no significant price variation across states. In his surrebuttal declaration, Dr. Cremieux correctly pointed out that there was significant price variation *between* plans due to individualized agreements between PBMs, pharmacies, plan members, and the plans.[224] Therefore, Dr. Rausser's analysis of state prices by plan eliminated

[219] Lakdawalla, Darius *et al*., "Intellectual Property and Marketing," *AEI-Brookings Joint Center for Regulatory Studies*, Working Paper 07-20, at 14 (2007) (Ex. 172).
[220] *Id.*
[221] Cremieux Decl. ¶¶ 102–03; Cremieux Merits Rep. ¶ 92–93.
[222] Cremieux Decl. ¶¶ 102–03; Cremieux Merits Rep. ¶ 92–93.
[223] Rausser Reply Decl., ¶¶ 42-48.
[224] Cremieux Surrebuttal ¶ 38.

an important source of price variability within and across states. As such, Dr. Rausser's analysis of prices by plan necessarily "eliminates the variation in prices that Dr. Rausser's average prices (which are based on highly aggregated data) mask."[225] In his January 8, 2014 deposition, Dr. Rausser introduced a new analysis and claimed that it also showed there is little variation in price across states, but the analysis was based on only a small sample of purchases by the named plaintiffs and again was conducted by plan.[226] In addition, Dr. Rausser's two analyses completely fail to respond to two important points. First, Dr. Cremieux makes clear that in the OptumHealth data prices vary substantially *within* each state, and second, the prices paid by consumers in Florida and Nevada were, a majority of the time during the class period, lower than the national average price.[227] Thus, using national average data, as Dr. Rausser proposes, would overcompensate many class members, and undercompensate others. Cremieux Decl. ¶ 103; *see also Espenscheid v. DirectSat USA, LLC*, 705 F.3d 770, 774 (7th Cir. 2013) (decertified class where plaintiffs' proposed damages model used inaccurate average data that would result in overcompensation of some class members and undercompensation of others).

Dr. Rausser himself recognizes the problems with using averages in a Rule 23 analysis: "Ignoring [price] variability by employing averages or median prices leads to an inaccurate and unfair damage estimate." Rausser Nexium Decl. ¶ 117; *see also, e.g., id.* at n.50 (criticizing the practice of "attempting to calculate classwide damages in reliance on means, averages, or distributions"). In fact, Dr. Rausser was chastised recently for failing to follow his own advice with respect to averages. In *Reed*, Dr. Rausser's opinion in support of certification was rejected, with the court writing that "[t]he first, and critical, flaw is [Rausser's] reliance on averages." 268

[225] Cremieux Surrebuttal ¶ 39.

[226] Rausser Rebuttal Rep. ¶ 115; Rausser Merits Dep. Tr. Ex. (109) 17:18–19:7.

[227] *See* Cremieux Decl. Exs. 13.1–13.3.

F.R.D. at 590–91. The court warned that using averages in a Rule 23 situation "can hide substantial variation across individual cases, which may be key to determining whether there is common impact." *Id.* at 591.[228] *See also, e.g.*, *Weiner v. Snapple Beverage Co.*, 2010 WL 3119452, at *9–10 (S.D.N.Y. Aug. 5, 2010) (rejecting reliance on averages for Rule 23 inquiry); *In re Flash Memory Antitrust Litig.*, 2010 WL 2332081, at *12 (N.D. Cal. June 9, 2010) (same); *In re Graphic Processing Unit Antitrust Litig.*, 253 F.R.D. 478, 493–94 (N.D. Cal. 2008) (same).

These fundamental flaws require rejection of the proposed classes. *See, e.g.*, *Blades v. Monsanto Co.*, 400 F.3d 562 (8th Cir. 2005) (affirming district court's denial of class certification based on the finding that individualized issues predominate as to damages); *Rodney v. Northwest Airlines, Inc.*, 146 Fed.Appx. 783 (6th Cir. 2005) (same); *Steering Committee v. Exxon Mobil Corp.*, 461 F.3d 598 (5th Cir. 2006) (same); *Stephens v. Seven Seventeen HB Philadelphia Corp. No. 2*, 2004 WL 1699331, at *5 (E.D. Pa. July 29, 2004) (denying motion for class certification because individualized issues predominated over common ones).

2. Plaintiffs' Model, at Best, Can Assess only Aggregate Damages, but Cannot Assign Damages to Individual Class Members

Comcast made clear that to satisfy Rule 23(b)(3) the plaintiff must show—at the class certification stage—that "damages are capable of measurement on a classwide basis" and that "*individual* damages calculations" will not "overwhelm issues common to the class." 133 S. Ct. at 1433 (requiring "damages [be] susceptible of measurement across the entire class."). *Comcast* represents a sea change in the law of class certification: whereas many courts had held that individual issues in calculating damages (as distinguished from assessing antitrust "impact")

[228] While the court in *Flonase* distinguished the criticism of Dr. Rausser in *Reed*, *Flonase* (1) did not have the substantial "no impact" evidence present here due, among other things, the high amount of samples and couponing, and brand loyalists; *see also* Cremieux Decl. ¶¶ 18–19, and (2) was decided before *Comcast* reinforced the need for evidentiary scrutiny of common impact issues. And, indeed, the *Flonase* court did find that "averaging" masked significant differences for uninsured patients and thus refused to certify a class including such individuals. 284 F.RD. at 230.

would not preclude certification, the Supreme Court made clear that Plaintiffs must show at the class certification stage that damages are capable of classwide assessments as well. *See Martins v. 3PD, Inc.*, 2013 WL 1320454, at *8, n. 3 (noting that in Comcast, the Supreme Court "has called . . . into question" the proposition that "courts generally find the predominance requirement satisfied even if individual damages issues remain").

Dr. Rausser's approach fails the *Comcast* standard because it seeks to show only that damages can be "calculated in the aggregate."[229] He admits that he has no method for avoiding "individual damages calculations" in the claims administration phase.[230] He just assumes a way will be found to deal with them at that time. But the tactic of calculating aggregated damages to be divvied up later cannot be squared with the teaching of *Comcast*. Indeed, such a "fluid recovery" approach was questionable in this Circuit and elsewhere even before *Comcast*. *OSB Antitrust Litig.*, 2007 WL 2253425, *14 (stating that "[a]warding damages through fluid recovery is controversial" and "several district courts in this Circuit have condemned it"); *see Windham v. Am. Brands, Inc.*, 565 F.2d 59, 72 (4th Cir. 1977) ("[T]he difficulties inherent in proving individual damages [cannot] be avoided by the use of . . . "fluid recovery."); *In re Hotel Tel. Charges*, 500 F.2d 86, 89–90 (9th Cir. 1974); *Eisen v. Carlisle & Jacquelin*, 479 F.2d 1005, 1018 (2d Cir. 1973) (fluid recovery is "illegal, inadmissible as a solution of the manageability problems of class actions and wholly improper"), *vacated on other grounds*, 417 U.S. 156

[229] Plaintiffs Amended Motion at 37.

[230] Rausser Merits Rep. ¶ 15 ("I understand that the division of class-wide damages between [insured consumers and their third-party payers] is a matter for claims administration and need not be resolved now."). Deferring determination of these issues for claims administration may be appropriate in the context of a settlement class, but it is not appropriate here. *See, e.g.*, *In re Skelaxin (Metaxalone) Antitrust Litigation*, 1:12-md-02343, Dkt. No. 508 (E.D. Ten. Jan. 30, 2014) ("The proposed "claims administration" procedure is wholly post-hoc whittling of the class in the context of settlement. This methodology does nothing for the individual fact-finding required if this case were put to a jury.").

(1974).[231] *Comcast* makes clear that reliance on an "aggregate" methodology where "individualized damage calculations" nonetheless will be needed is improper.

Moreover, a claims administrator is simply not equipped to deal with the complex "no impact" inquiries reviewed above. Individualized assessments designed to address these complexities would present precisely the type of labyrinthine calculations rejected by *Comcast* and other courts. For example, as explained above, a host of highly variable consumer and TPP-specific factors affect the net effective prices paid by the three subgroups in both the actual and but-for worlds. These factors include:

- The amount of co-pays / co-insurance and other plan benefit design factors (insured consumers and TPPs);
- The use of samples (all subgroups);
- The use of coupons (insured and uninsured consumers);
- Deductibles and coverage limits (insured consumers and TPPs);
- The receipt of manufacturer rebates (TPPs);
- The nature and extent of risk sharing with other entities (TPPs);
- Retail pharmacy reimbursement rates (TPPs);
- The cash register price at the retail pharmacy, which is affected by markups at the manufacturing, wholesale and related levels (insured and uninsured consumers); and
- The time period when the drug was purchased (all subgroups).

To assess impact, and ultimately damages, these factors would have to be addressed on an individual basis for each class member and each transaction.

[231] *In re Pharm. Average Wholesale Price Litig.*, 582 F.3d 156, 197 (1st Cir. 2009) does not help Plaintiff because in that case, unlike here, plaintiff's damages test "sufficiently incorporated individualized information about the class members to support the district court's decision to adopt it for the entire class." *In re Terazosin Hydrochloride*, 220 F.R.D 672, 699 (S.D. Fla.2004) has been called into question by *In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 287 (D. Mass. 2004), which criticized *Terazosin* for failing to refer to or analyze Florida law and held that Florida law "require[d] a somewhat stronger and more precise showing of individual impact" than the aggregate approach being proposed.

A similar web of complex, individualized factors would affect the amount of brand and generic purchases in the but-for world. As discussed above, these factors include:

- Number of generic entrants and timing of each entry;
- Nature and extent of marketing support for branded and generic products;
- Level of brand loyalty of insured and uninsured consumers; and
- Effects of TPPs driving utilization to generic products through, for example, changes in co-pays, prior authorization requirements, and similar tactics.

Analyzing these variable factors on an individualized basis would be a massive undertaking.

F. Plaintiffs Cannot Satisfy the Rule 23(a) Requirements

1. IBEW and IUOE are Inadequate Class Representatives—They Have no Financial Stake in the Litigation and There Is an Inherent Antagonism between the Proposed Class Representatives and Members of the Class, and Among Class Members Themselves

In *Dewey v. Volkswagen*, 681 F.3d 170 (3rd Cir. 2012), the Third Circuit explained that "[a] fundamental conflict exists where some [class] members claim to have been harmed by the same conduct that benefitted other members of the class." *Id*. at 184 (citation omitted). As discussed above, the proposed classes here are rife with "winners" and "losers" in a world assuming entry of generic Doryx capsules beginning in 2006. Certification is inappropriate in the face of such differing interests.

[redacted]

[redacted]

[redacted] Simply put, Plaintiffs offer no evidence that they would have benefitted in Dr. Rausser's hypothetical but-for world. [redacted]

Second, IBEW and IUOE have little-to-nothing in common with either the insured or the uninsured consumer members of the proposed classes. Plaintiffs certainly have nothing in common with the *consumer* members of the classes. The incentives and payment obligations of the two groups are very different. Nor do the class representatives have anything material in common with insurance giants such as Kaiser Permanente, Blue Cross-Blue Shield, and other sophisticated health insurers covering millions of patients, as Plaintiff IBEW and IUOE only have approximately 6,000 and 3,000 insureds, respectively.

Third, there are inherent conflicts between the claims of insurance providers, such as IBEW and IUOE, and insured consumers. For every prescription subject to a claimed overcharge, insurers and insureds will have to "split" that overcharge between them. Each will have an interest in maximizing its share. Plaintiffs consequently have an interest in maximizing the allocation of aggregate damages in favor of the TPP segment of the class, to the detriment of the uninsured consumer segment of the class. This incentive has been manifest in Plaintiffs' manipulation of the class definitions. Plaintiffs have been willing to eliminate *consumers* from the class definition—*i.e.*, insured individuals covered by plans imposing flat co-pays, consumer

[redacted]

who purchased branded Doryx with a coupon (and never without a coupon), and all *consumer* transactions involving a coupon—but unwilling to exclude TPPs that could not be part of any class (assuming contrary to fact that any class were appropriate).[234] These conflicts alone render Plaintiffs inadequate as a class representative. *See, e.g., Pickett v. IBP Inc.*, 182 F.R.D. 647, 653 (M.D. Ala. 1998) ("[C]ourts have found that Rule 23 requirements are not satisfied where some class members are given an advantage, while others are put at a disadvantage."); *Katz v. Comdisco, Inc.*, 117 F.R.D. 403, 408 (N.D. Ill. 1987) (denying class representative status to individual who benefited from alleged activity while class members were harmed); *Auto Ventures, Inc. v. Moran*, 1997 WL 306895, at *5 (S.D. Fla. April 3, 1997) (rejecting class certification where proposed class representatives may have been forced to argue that they actually benefited by alleged antitrust activity); *Bieneman v. City of Chicago*, 864 F.2d 463, 465 (7th Cir. 1988) (denying class certification where some of the proposed class members "undoubtedly derive great benefit" from the challenged action and proposed class representative, therefore, conflicted with interests of some class members).

There is also an inherent conflict between plan sponsors (like IBEW and IUOE) and other TPPs who are "on the risk" for particular reimbursements. Given the myriad risk transfer and risk sharing arrangements among TPPs, there will be conflicts between and among pharmacy benefits managers, claims administrators, full or partially self-funded employers and union funds such as IBEW and IUOE over which TPP is ultimately financially responsible for any particular prescription reimbursement. As discussed above, the entity that actually reimburses the pharmacy may be performing a simple claims administration function, with a self-funded employer or health insurance company actually responsible, at least in part, for the

[234] Plaintiffs Amended Brief at 2–4.

reimbursement. Each has an interest in claiming responsibility for the prescription. The classes as defined are likely to be rife with conflicts over who "paid" for each prescription.

2. Plaintiffs Have Failed to Meet Their Burden of Proving the Proposed Classes Are Sufficiently Numerous and that Class Members Are Ascertainable

a. Dr. Rausser's Numerosity Declaration Relies on "Probabilistic" Class Memberships and Speculation and Fails to Remove Consumers and TPPs that Were Unharmed by the Alleged Delay

Plaintiffs rely solely upon Dr. Rausser's Supplemental Declaration to carry their burden of proving that the proposed classes meet the numerosity requirement of Rule 23(a). Dr. Rausser's analysis, which reviews consumers and TPPs separately, fails to show anything relevant because it relies on "probabilistic" class membership, inapposite data and unsupported speculation.

Speculation about TPPs and "probabilistic" class membership. Dr. Rausser's work can be summarized as follows. He first computes the number of Doryx prescriptions for each of the three relevant states during the class period, removing only transactions with consumer coupons (although this carve-out is far too small as explained below).[235] Next, he determines the average number of prescriptions used by each patient ***nationwide***, and applies that average to the number of prescriptions he calculated for each region to get an estimated number of patients who purchased Doryx in each relevant state.[236] Last, he removes consumers with flat co-pays by adjusting his calculation by 6%, to reflect the "average" number of health plans with flat co-pays from 2008 to 2012.[237]

[235] *See* Rausser Supp. Decl. ¶ 5a, b.
[236] *See id.* ¶ 5c.
[237] *See id.* ¶ 5d.

At best, Dr. Rausser's calculation ***estimates*** the number of consumers who do not, ***on average***, have flat co-pays. But that calculation (even if it were reasonable, which it is not) provides no information about the number of consumers in each of the respective classes. Ineligible class members, such as brand loyal users, consumers not impacted because of deductible or other insurance plan features, and consumers not impacted because of their use of coupons and/or samples,[238] should have been excluded but were not. Moreover, removing only coupon *transactions* improperly inflates the number of class members,[239] because it still leaves in the class *all* consumers who used a coupon, and also purchased Doryx at least one time without using a coupon, even though many of these consumers likely were not impacted.[240] *See supra* Part III.D.1.b. Also, state-specific data should have been used instead of national averages. Dr. Rausser simply assumed that duration of use and number of prescriptions filled per patient would not vary between states,[241] but he did nothing to test this assumptions, which for examples ignores a feature of Doryx (light sensitivity) that may impact its use in one state (*e.g.*, Florida) versus other states.[242]

Speculation about TPPs. As Dr. Cremieux explained, Dr. Rausser's assessment of TPPs in the proposed classes is "entirely theoretical" and is better classified as an estimation of which

[238] *See supra* Part II.B (discussing proposed class definitions).

[239] *See* Supplemental Declaration of Pierre-Yvez Cremieux (Ex. 1), dated January 31, 2014, ¶¶ 9–12 ("Cremieux Supp. Decl."); *see also* Cremieux Merits Rep. ¶¶ 98–99 ("Thus, not only do unharmed individuals remain in the class, but Dr. Rausser's proposed damages method also incorrectly assigns them damages, causing class-wide damages to be overestimated.").

[240] Plaintiffs Amended Brief at 2–4 (discussing definition of proposed classes).

[241] Rausser Supp. Decl. ¶ 5c.

[242] *See* April 2013 Doryx Label (Ex. 173) (indicating that "Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines.").

plans "*would have* covered Doryx during a particular period."[243] But the Court already rejected that type of information as insufficient.[244]

Rather than use data about actual reimbursements, Dr. Rausser uses formulary data at only a single point in time (specifically July 14, 2010) and concludes, without support, that this would be similar for the rest of the class period.[245] But formularies change over time, and picking a single day as representative of a 4+ year period bears no connection to reality.[246]

Dr. Rausser then follows a series of convoluted estimates to arrive at the "probability" that each TPP might have reimbursed a single Doryx purchase. As shown on Table 1 below, Dr. Rausser estimates that, for example, the self-insured plan Winderweedle, Haines, et al has a 19% probability of a Doryx reimbursement, while the University of Florida Foundation Cafeteria Plan has an 18.7% percent change of a Doryx reimbursement. Dr. Rausser assigns each potential class member its own "probability assessment," which are then summed across all potential class members to reach Dr. Rausser's "estimate of the number of health plans that paid for Doryx during the class period."[247] Simply stated, Dr. Rausser's logic is that if there are 10 TPPs that cover Doryx, and there is a 20% probability that each one reimbursed a single Doryx prescription, then there are 2 members in the class (10 times .2).

[243] Cremieux Supp. Decl. at ¶ 14.

[244] *See* Order at 4.

[245] Rausser Supp. Decl. ¶ 7b; *see also* Cremieux Supp. Decl. ¶ 16.

[246] [redacted]
Rausser Supp. Decl. 7d.

Table A:
Examples of Employer Self-Insured Plans Paying for Doryx in Florida
Based on Dr. Rausser's Methodology

No.	Employer Id. No.	Plan Name	Contribution to the Total Number of Self-Insured Plans Paying for Doryx
1	591295597	WINDERWEEDLE, HAINES, WARD & WOODMAN, P.A. EMPLOYEE BENEFIT HEALTH PLAN TRUST	0.190
2	590974739	UNIVERSITY OF FLORIDA FOUNDATION CAFETERIA PLAN	0.187
3	590810731	YMCA OF SUNCOAST, INC. MEDICAL PLAN	0.186
4	593252776	EMI INDUSTRIES LLC WELFARE BENEFIT AND SEC 125 PLAN	0.185
5	592142739	HARDEN & ASSOCIATES, INC. HEALTH AND WELFARE PLANS	0.185
6	592742907	AVMED, INC. HEALTH REIMBURSEMENT ARRANGEMENT PLAN	0.184
7	591058089	CANTERBURY SCHOOL CAFETERIA PLAN	0.184
8	263799591	PLASMA-THERM, LLC HEALTH AND WELFARE PLAN	0.184
9	320077432	EQUITY GROUP LEASING I, INC. ERISA HEALTH PLAN	0.184
10	651049847	CYPRESS PARTNERS LLC EMPLOYEE BENEFITS PROGRAM	0.182
11	450505032	GROUP MEDICAL INSURANCE FOR EMPLOYEES OF CTI RESOURCE MANAGEMENT SERVICES, INC.	0.182
12	271306016	INNER CIRCLE MANAGEMENT HEALTH & WELFARE PLAN	0.181
13	260700429	MEDICAL HAIR RESTORATION, INC. WELFARE PLAN	0.180
14	454662986	FALCK SE II CORPORATION WELFARE PLAN	0.178
15	650967864	KNIGHT ENTERPRISES EMPLOYEE BENEFIT PLAN	0.177
		Total	2.749

Dr. Rausser provides no support for this methodology. He has done little more than conclude that there are a number of TPPs that at least on one day during the class period covered Doryx and that some of them must have reimbursed for Doryx. His "calculation" provides no relevant information regarding which TPPs fit the proposed class definition, because it does nothing to identify the TPPs supposedly impacted by the alleged conduct.

Plaintiffs thus have failed to carry their burden of showing that the proposed classes are sufficiently numerous.

b. Plaintiffs Have Failed to Provide a Method for this Court to Ascertain the Class Members and Failed to Show Plaintiffs Themselves Are in Any of the Classes

"It is elementary that in order to maintain a class action, the class sought to be represented must be adequately defined and clearly ascertainable." *DeBremaecker v. Short*, 433 F.2d 733, 734 (5th Cir. 1970); *see In re Sch. Asbestos Litig.*, 56 F.3d 515, 519 (3d Cir. 1995); *Chakejian v. Equifax Info. Servs.*, 256 F.R.D. 492, 497 (E.D. Pa. 2009) (stating a proposed class must be "adequately defined and clearly ascertainable"); 7A Wright & Miller, FEDERAL PRACTICE AND PROCEDURE, § 1760 (3d ed.) (The class description must be "sufficiently definite so that it is administratively feasible for the court to determine whether a particular individual is a member."). For a court to consider certifying a class, a plaintiff must first define the class with reference to objective criteria and must provide a reliable and administratively feasible mechanism to determine whether putative class members fall within the class definition. *See Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 593-94 (3d Cir. 2012). *See also* William B. Rubenstein & Alba Conte, *Newberg on Class Actions*, § 3:3 (5th ed. 2011) ("Administrative feasibility means that identifying class members does not require much, if any, individual factual inquiry."). The Third Circuit has strictly required identification of class members to be free from extensive fact-finding or speculation, *see Marcus*, 687 F.3d at 593, and has noted that "[a]scertainability mandates a rigorous approach at the outset because of the key roles it plays as part of a Rule 23(b)(3) class action lawsuit." *Carrera v. Bayer Corp.*, 727 F.2d 300, 306 (3d Cir. 2013).

Plaintiffs have failed to set forth *any* criteria by which this Court can determine membership in the classes, without requiring individualized analysis of each separate class member. On the TPP side, given the complex web of risk-sharing arrangements among insurers,

PBMs, employers and other intermediaries, as well as the role of the federal and state governments in funding even "private" insurance (through, for example, Medicare Part D plans), it would be a complex and individualized task to identify which entities actually fit the class definition.[248] To take just one example, PBMs generally administer pharmacy benefits for insurers, self-funded employers and others. PBMs usually deal directly with pharmacies, not the insurance provider [redacted]. Thus PBMs, and not insurers, typically pay pharmacies for prescription drugs in the first instance. Sometimes the PBM is a mere pass-through, and the insurance company or self-funded employer ultimately is responsible for the prescription reimbursement cost. Sometimes PBMs take on some level of risk for reimbursement costs. For example, PBMs may bear the risk of the "spread" between amounts they pay pharmacies for prescriptions and amounts insurers reimburse the PBMs. PBMs negotiate separate contracts with pharmacies and insurers, with separate reimbursement rates for various drugs. To the extent there was an "overcharge" here, PBMs therefore could have borne a portion as a result of the spread between their pharmacy and insurer reimbursement formulas.[249] In other instances, PBMs enter into "risk sharing or shared services agreements(s)" in which "the client and the PBM both assume some risk for the total cost of the prescription drug program."[250] Such agreement may include guarantees on "per member annual drug spending" and "annual trending drug spending." Insurers would bear part of the ultimate cost, but dividing responsibility would be complex. Plaintiffs propose no methodology for addressing these issues.

[248] *See, e.g.*, Cremieux Decl. ¶ 60; *supra* III.D.1.d.

[249] Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, August 2005 at 9–10 ("FTC PBM Study") (Ex. 174).

[250] Health Care Financing Administration Study of Pharmaceutical Benefit Management, undertaken by PricewaterhouseCoopers LLP, June 2001 ("HCFA PBM Study") at 91, 100 (Ex. 175).

The *In re Skelaxin* court recently addressed these very same issues and rejected class certification. 1:12-md-02343, Dkt. No. 508 (E.D. Ten. Jan. 30, 2014). In that case, the court refused to certify an end payer class in a delayed generic case because "the question of who paid or reimbursed a portion of the purchase price for Skelaxin . . . [is] a question with no simple resolution . . . that would require a transaction-by-transaction inquiry" in order to determine which entities or individuals are included in the class. *Id.* at 2, 26–27. *In re Skelaxin* involved the same complex web of insurers, employers, PBMs, and other intermediaries as potential end payer class members. *Id.* at 3, 11–12. The court held that because Dr. Rausser had not proposed a method of evaluating the complex web of risk sharing and other contractual arrangements class certification was not proper. *Id.* at 22–23. ("Dr. Rausser, for his part, characterized this as a "claims administration" issue to be addressed following a determination of liability.").

On the consumer side, Plaintiffs and Dr. Rausser likewise have failed to provide an approach to identify who was injured without individual fact-finding. For example, Plaintiffs have provided no feasible way to identify individuals who should be carved-out of the class. How can it be determined which consumers were subject to flat co-pays during the class period without individual fact finding, or which ones used coupons and/or samples so that overall they were not impacted? Further, it is simply impossible to determine who would have been a brand loyalist in the hypothetical but-for world—a group which accounts for, *at a bare minimum*, through Dr. Rausser's own methodology, 6% of the consumer part of the class (most likely more).[251]

Again, Plaintiffs' approach presents the same type of flaws rejected by courts. For example, in *Hayes v. Wal-Mart Stores, Inc.* 725 F.3d 349 (3d Cir. 2013), the court explained that

[251] *See supra* III.D.1.a-c.

it was plaintiffs' burden under Rule 23 to "show by a preponderance of the evidence that there is a reliable and administratively feasible method for ascertaining the class." *Id* at 356. The court found that plaintiffs could not show which of 3,500 transactions would qualify for class membership and thus denied certification. *Id*. at 357. Plaintiffs' motion in this case should suffer the same fate because Plaintiffs and Dr. Rausser have failed to provide any systematic way to determine who is in the proposed classes and who is not.

G. Plaintiffs' Proposed Injunction Class Fails Because It Is Redundant of the Claims Asserted by Multiple Other Plaintiffs And Ill-Defined

Even if this Court determines that Plaintiffs' proposed injunction class meets the appropriate requirements of Rule 23(a) and Rule 23(b)(2), this Court "may nevertheless deny class certification" where "all the class members will benefit from an injunction issued on behalf of the named plaintiffs." *Mills v. District of Columbia*, 266 F.R.D. 20, 22 (D.D.C. 2010); *see Blake v. Chemlawn Servs. Corp.*, 1988 WL 6151 at *4–*5 (E.D. Pa. Jan. 26, 1988). As this Court has stated, "an individual plaintiff can also obtain injunctive relief and, if this court renders a decision favorable to the individual plaintiffs, any relief will benefit automatically all potential class members. It will thus have the purpose and effect of a class action." *Blake*, 1988 WL 6151, at *5.

This is precisely the situation here. Multiple plaintiffs have moved this Court for injunctive relief. Any injunctive relief that could be granted by the Court would benefit the proposed members of the class. Thus, the class action device is not necessary for the federal injunction class.

In any event, the Plaintiffs' injunctive relief claims are too ill-defined to support a class action. Plaintiffs' seek to "enjoin[] Defendants from withdrawing prior formulations of Doryx

from the market while introducing new formulations with no additional therapeutic benefit."[252] But this indefinite and amorphous statement regarding "future" harm ignores the facts, which show that multiple manufacturers now market generic Doryx, and Warner Chilcott's most recent introduction (200 mg) includes a new therapeutic indication. There simply is no credible claim of potential future harm and no conduct to enjoin. At a bare minimum, the absence of any detail in Plaintiffs' cursory (one page) discussion of the proposed injunctive fails to meet the standard of Rule 23(b)(2).[253]

CONCLUSION

For the forgoing reasons, the Court should deny Indirect Purchaser Plaintiff's motion for class certification.

[252] Plaintiffs Amended Brief at 27.

[253] Plaintiffs Amended Brief at 26–27.

Respectfully submitted this 31st day of January, 2014.

By: /s/ J. Mark Gidley

J. Mark Gidley
Peter J. Carney
WHITE & CASE LLP
701 Thirteenth Street, NW
Washington, DC 20005-3807
Telephone No.: 202-626-3600
Fax No.: 202-639-9355
mgidley@whitecase.com
pcarney@whitecase.com

and

Jack E. Pace III
Michael J. Gallagher
WHITE & CASE LLP
1155 Avenue of the Americas
New York, New York 10036-2787
Telephone No.: 212-819-8200
Fax No.: 212-354-8113
jpace@whitecase.com
mgallagher@whitecase.com

By: /s/ Edward D. Rogers

Edward D. Rogers
Jonathan Satinsky
BALLARD SPAHR LLP
1735 Market Street
Philadelphia, Pennsylvania 19103-7599
Telephone No.: 215-665-8500
Fax No.: 215-864-8999
rogerse@ballardspahr.com
satinskyj@ballardspahr.com

Attorneys for Defendants Warner Chilcott Public Limited Company, Warner Chilcott LLC, Warner Chilcott (US), LLC, Warner Chilcott Holdings Company III, Ltd., and Warner Chilcott Laboratories Ireland Ltd.

CERTIFICATE OF SERVICE

I, Jack E. Pace III, hereby certify that on January 31, 2014, I caused true and correct copies of the Factual Appendix In Support Of Defendant Warner Chilcott's Opposition to Indirect Purchaser Plaintiff's Amended Motion for Class Certification to be served by electronic mail and FTP server upon all counsel of record.

By: /s/ Jack E. Pace III

Jack E. Pace III
WHITE & CASE LLP
1155 Avenue of the Americas
New York, NY 10036-2787
Telephone No.: 212-819-8200
Fax No.: 212-354-8113
jpace@whitecase.com